IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON
TRANSCRIPT OF PROCEEDINGS

JACQUELYN TYREE, et al., **CIVIL ACTION NO.**

Plaintiffs, **2:12-cv-08633**

v.

BOSTON SCIENTIFIC CORPORATION,

Defendant.

TRIAL DAY TWO

NOVEMBER 03, 2014

BEFORE THE HONORABLE IRENE C. BERGER,

UNITED STATES DISTRICT JUDGE

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Proceedings recorded by machine stenography; transcript produced by computer.

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I N D E X

PROCEEDINGS had before The Honorable Irene C. Berger, Judge, United States District Court, Southern District of West Virginia, in Charleston, West Virginia, on November 03, 2014, at 9:00 a.m., as follows:

THE COURT: Good morning, everyone.

Ladies and gentlemen, I have some pre-trial instructions that I want to give you this morning before we begin the trial.

You have been selected as jurors and have taken an oath to well and truly try this case. And as I've indicated to you, I expect the trial to last approximately ten and a half working days.

During the trial, there will be times, as you know, that I will take breaks or recesses. During those times, you must not talk about this case among yourselves or with anyone else.

Further, you are instructed not to permit anyone to discuss the case in your presence. This instruction goes to your family and friends as well.

It is your sole and exclusive responsibility in the case to decide the case solely upon the law and evidence without help and assistance from persons other than your fellow jurors.

You will find yourselves together in the jury room in the mornings before trial, in the afternoon after lunch, and

at various other times. Even though you are all together, you're not to discuss this case until I release you to deliberate your verdict at the conclusion of the case.

Further, you are instructed not to conduct any independent investigation or research the facts and circumstances of the facts or research the law related to the case, nor are you to use a dictionary, computer, or other reference materials including but not limited to Bing, Google, or any other research tool to define terms or gain knowledge about issues or people, including the lawyers, which you hear about during the course of this trial.

You may not communicate with anyone about the case on your cell phone, through e-mail, Blackberry, text messaging, or on Twitter, through any blog or website, through any internet chat room, or by way of any other social networking websites, including but not limited to Facebook, Myspace, LinkedIn, and YouTube or, of course, by any other means.

Until you retire to deliberate, you may not discuss the case, again, with anyone, even your fellow jurors.

After you retire to deliberate, you may begin discussing the case with your fellow jurors, but you cannot discuss the case with anyone else until you have returned a verdict and the case is at an end. You must also keep each other honest. Therefore, I will expect you to inform me if you become aware of a juror violating these instructions.

You may take notes. On your chairs you have found notepads and pens. Your notes are not evidence and should not take the place of listening to or watching witnesses.

Do not rely on someone else's notes or recollections. When you leave the courtroom, place your notepads face down. No one will look at them and the room will be secured each night.

You're further instructed not to take any photographs or videos with your cell phones of fellow jurors or of any part of the court proceedings.

During the trial, do not talk to any of the plaintiffs or defendants or lawyers or any of the witnesses. As I told you on Friday, if you see any of the parties seated at counsel table on the elevator or outside on the sidewalk and say "good morning" to them, they are likely to shy away from you. That's not intended as any arrogance or unfriendliness on their parts. They are simply trying to keep my instruction that they stay clear of you ladies and gentlemen as well.

If anyone tries to talk to you about any of the matters under consideration in this trial, you should immediately report that to me or to the court security officer.

There will be people meeting in other rooms while you all are in the jury room. So, be sure to keep your jury room

door closed whenever possible. If you hear anything about the case while you're in the jury room, be sure to let me know.

It is a Judge's responsibility to preside over a trial impartially and without favor to either side. So, while judges may exhibit certain attitudes or may make rulings for one side or another in any given situation, you should not take this in any way as any indication that the Judge wishes you to reach a certain result in the case.

You should keep an open mind. You should not form or express a final opinion on any issue during the trial. You should keep from reaching a conclusion on the case until you have heard all of the evidence, the arguments of the attorneys, and the final instructions on the law that I will give to you after you have heard all of the evidence.

You must not permit yourself to be influenced by sympathy, bias, passion, or favor as to either side. Remember, you have a duty to discuss the case with your fellow jurors during deliberations prior to reaching a conclusion in the case.

This is a consolidated trial of four separate cases filed by four separate plaintiffs against Boston Scientific. Although the evidence will be presented in one trial together and although some evidence may overlap, you must consider each plaintiff and her individual claims separately from the others. That is, treat each case separately as if each have

been tried by itself.

In that regard, you may not consider facts that relate specifically to only one plaintiff as to any other plaintiff. You may not even consider that more than one claim was brought when reaching your verdict as to a particular plaintiff.

Likewise, as to Boston Scientific's defenses, you must consider its defenses separately with respect to each plaintiff.

At the end of the trial, you will be asked to decide each of the cases separately, and your decision for each case must rest on the merits of each plaintiffs' individual claims and on the merits of Boston Scientific's defenses as to each plaintiffs' claims.

You ladies and gentlemen as jurors are the judges of the facts. You must apply the facts as you find them to the law as I will give it to you in these instructions and in later instructions.

In a civil case such as this, the plaintiff has the burden of proving each and every element of her case by a preponderance of the evidence. To prove by a preponderance of the evidence means to prove that something is more likely so than not so.

When more than one claim is involved and when more than one defense is asserted, you should consider each claim

and defense separately. But in deciding whether any fact has been proven by a preponderance of the evidence, you may consider the testimony of all of the witnesses, regardless of who may have called them, and all exhibits received in evidence, regardless of who may have produced them.

You must base your verdict solely upon the evidence presented in the case. The evidence consists of the sworn testimony of the witnesses, the exhibits, stipulations, and those matters of which I take judicial notice.

When the parties stipulate or agree that a fact is true, you may consider the fact to be true. During the trial I may take judicial notice of a fact. You may consider that fact to be true.

Many of you raised your hands when I asked about television commercials related to pelvic mesh. Understand that the fact that lawyers are advertising on television for pelvic mesh cases or even the fact that there are more pelvic mesh claims being made is not evidence whatsoever. You shall not consider any of this in your deliberations in this case.

The defendant has been brought to trial only for the claims made by the plaintiffs in this lawsuit. Therefore, each plaintiff in this case has the burden of proving that the particular product in this -- the Obtryx was defectively designed and not accompanied by adequate warnings. You may not speculate about the existence or nonexistence of other

claims or the merits or demerits of any such claim.

I may instruct you that evidence can only be used for a limited or particular purpose. Consider any evidence admitted for a limited purpose only for that limited purpose.

Now, I will instruct you on how to view some of the events that are likely to occur during the trial.

Initially, ladies and gentlemen, the attorneys will have an opportunity to make opening statements. Counsel for the plaintiffs will make an opening statement first. Then counsel for the defendant may, but does not have to, make an opening statement.

These statements should be considered only as a preview of what the attorneys expect the evidence in the trial to be. These statements are not evidence.

Next, witnesses will be called to testify. They will be placed under oath and questioned by the attorneys. First, counsel for the plaintiffs will present witnesses through direct examination, and counsel for the defendant can cross-examine them if there is cross-examination. Then counsel for the plaintiffs will have an opportunity to redirect the witnesses.

At the conclusion of the plaintiffs' case, counsel for the defendant may, but is not required to, call witnesses. Counsel for the plaintiffs will have the opportunity to cross-examine those witnesses. If that occurs, counsel for

the defendant will conduct redirect examination if he or she chooses.

You, ladies and gentlemen of the jury, will determine the credit and weight you will give to the testimony of each witness. In doing this, you can consider, if found by you from the evidence, his or her good memory or lack of memory; his or her interest or lack of interest in the outcome of the trial; the intelligence or lack of intelligence of the witness; his or her demeanor and manner of testifying; his or her opportunity and means or lack of opportunity and means of having knowledge concerning the matters which he or she testifies; the bias, prejudice, hostility, friendliness or unfriendliness of the witness for or against any of the parties; the relationship of any witness to any of the parties or other witnesses; the reasonableness or unreasonableness of the witness's testimony; and his or her apparent fairness or lack of fairness.

At times witnesses may appear by deposition testimony read to you from a written transcript or shown by videotape recording consisting of answers under oath to questions asked of the witness in advance of the trial in the presence of a court reporter. These depositions are taken out of the presence of the Court.

The testimony of a witness who for some reason cannot be present to testify from the witness stand is entitled to

the same consideration and is to be judged as to credibility and weight as if the individual had been present and had testified here from the witness stand.

Also, during the trial I might receive documents and other exhibits as evidence. If evidence is given to you to examine, you should examine it carefully without comment and remember that you will have another opportunity to examine the evidence during the course of your deliberations.

You should also know that it is an attorney's right and duty to object when testimony or other evidence is being offered that he or she believes should not be admitted into evidence. When I decide that an objection is correct, I will sustain it and you should act as if you never saw the evidence or heard the attorney's question or the witness's answer if given.

There also may be times when I will strike evidence from the record. You should act as if this evidence never existed.

However, if I decide that an objection is not correct, I will overrule it and you should give that evidence no more or less weight than if the objection had not been made.

Sometimes an attorney will request a bench conference or a recess to discuss an objection. That's not intended to hide or conceal anything from you ladies and gentlemen of the

jury. But it is designed to ensure that only relevant and legally admissible evidence is presented in your presence.

There may be times that I will refuse a bench conference or recess and you should draw no inferences from that whatsoever.

Finally, the attorneys will make closing arguments. These arguments, like opening statements, are not evidence. The attorneys at this time are permitted to summarize the evidence and the law and try to persuade you to decide on a particular verdict.

You as jurors may accept or reject these arguments as you see fit. If any argument, statement, or remark of counsel is not consistent with the evidence or with my instructions on the law, then you should disregard that argument, statement, or remark.

I'm going to give you detailed instructions on the law at the end of the case. But in order to help you follow the evidence, I will give you a brief summary of what each of the plaintiffs must prove to make their case in connection with each cause of action.

The plaintiffs have claims for strict liability for design defect, strict liability for failure to warn, and negligence.

Also, one of the plaintiffs' spouses -- one of the plaintiffs' spouse has a claim for loss of consortium. I will

give you a brief overview of these claims.

The defendant, Boston Scientific, denies these claims.

The plaintiffs contend that they were each injured as a result of implantation of the defendant's product, the Obtryx. The plaintiffs' first claim is that the Obtryx was defectively designed. To recover damages for a defectively designed product, a person injured by the allegedly defective product must establish the following elements by a preponderance of the evidence:

First, that the allegedly defective design conditions existed in the Obtryx product at the time it left the control of Boston Scientific; that the allegedly defective conditions, secondly, made the Obtryx not reasonably safe for its intended use; third, that the plaintiff was injured; and, fourth, that the plaintiffs' injuries were proximately caused by the allegedly defective conditions of the Obtryx.

The proximate cause of an injury is the last negligent act contributing to the injury and without which the injury would not have occurred. Proximate cause must be understood as that cause which in actual sequence unbroken by any independent cause produced the event without which such event would not have occurred.

I will explain what, quote, "not reasonably safe for its intended use" means at the end of this trial.

The plaintiffs also bring a claim in strict liability for failure to warn. The plaintiffs contend that the Obtryx sling was not reasonably safe for its intended use because it lacked adequate warnings. Because the Obtryx can only be obtained through a physician, the defendant had a duty to adequately warn only the physicians who implant the Obtryx.

The defendant did not have a duty to warn consumers such as the plaintiffs. Any evidence or argument that Boston Scientific owed a -- or breached a duty to warn the plaintiffs directly is improper and it may not be considered in reaching your verdict.

To recover damages for failure to warn and strict liability, a plaintiff must establish the following elements by a preponderance of the evidence:

First, that the defendant failed to provide adequate warnings to the plaintiffs' physician; secondly, that the lack of adequate warnings made the Obtryx not reasonably safe for its intended use; third, that the plaintiff was injured; and, fourth that the plaintiffs' injuries were proximately caused by the lack of adequate warnings to the plaintiffs' physician by the manufacturer.

The plaintiffs have also made a claim for negligence. Broadly, defendants had a duty to use ordinary care for the plaintiffs' safety. Negligence means the failure of a person to use due care or to do something that a reasonable and

prudent person would do in the same or similar circumstances.

On the other hand, negligence may be the doing of something that a reasonably prudent person would not do in the same or similar circumstances. The plaintiff, plaintiffs allege that the defendant was negligent in two ways.

First, the plaintiffs allege that the defendant was negligent in its design of the Obtryx. To recover damages as a result of negligent design, a plaintiff must prove by a preponderance of the evidence that Boston Scientific was negligent and that that negligence was the proximate cause of the plaintiffs' injuries.

The plaintiffs' second theory of negligence is that the defendant was negligent in failing to provide adequate warnings. You should remember that the defendant did not have a duty to warn consumers such as the plaintiffs but, instead, had a duty to warn their physicians as learned intermediaries.

To recover damages as a result of negligent failure to warn, a plaintiff must prove by a preponderance of the evidence Boston Scientific was negligent and such negligence was the proximate cause of the plaintiffs' injuries.

For both negligence claims, proximate cause is that cause which in actual sequence unbroken by an independent cause produced the wrong complained of without which the wrong would not have occurred.

The proximate cause of an injury is the last

negligent act contributing to the injury and without which the injury would not have occurred.

Additionally, Mr. Tyree brings a claim for loss of consortium. Consortium is a right arising from the marital union to have performance by a spouse of all the duties and obligations assumed by the marriage relationship including the right to society, companionship, and services.

As I've indicated to you on Friday, ladies and gentlemen, do not read any newspaper accounts or listen to any radio or view or listen to any television or internet coverage that there might be of the trial. You are instructed to completely disregard such information and decide the issues solely on the basis of the facts and law presented to you here in this courtroom.

To help ensure that your decision is based only on the law and the facts, the jury room door should remain closed at all times. For your planning, I believe I indicated to you on Friday we will generally begin court at 9:00 a.m. and conclude somewhere as close to 5:00 in the evening as we can.

If at any time during the course of the trial you become tired or have difficulty hearing or seeing or experience any discomfort such that it is necessary to take a break, please feel free to raise your hand.

At this point, ladies and gentlemen, you will hear the opening statements that I referred to here in these

instructions after you take your oath.

(Jury panel sworn)

THE COURT: Counsel for the plaintiff, will you go forward with opening?

MR. LOVE: We're ready to proceed, Your Honor.

THE COURT: Mr. Love.

MR. LOVE: Your Honor, I've been requested to ask you to turn on the main monitor.

THE COURT: All right. Did I do it?

MR. LOVE: You did, ma'am.

THE COURT: Thank you.

MR. LOVE: May I proceed, Your Honor?

THE COURT: Yes, sir.

MR. LOVE: Good morning.

You and I haven't been properly introduced. My name is Scott Love. And on behalf of my colleagues, Paul Farrell, Aimee Wagstaff, and Doug Monsour, we have the pleasure to represent these four fine ladies here, Jacquelyn Tyree, Carol Campbell, Jeanie Blankenship, and Chris Wilson.

You're going to get to hear their story as this trial develops. You're going to get to hear how their lives have been impacted by the Obtryx sling.

And this is a pretty simple case. My clients experienced a pretty common condition called stress urinary incontinence. And you're going to hear quite a bit about that

throughout the course of this trial.

This company here made a product called the Obtryx sling that was supposed to help, but didn't.

Boston Scientific, you may ask: What do they do? As you might suspect, they're a company that's located right outside of Boston, Massachusetts. This is a medical device company, one of the ten largest in the world that makes medical devices, many of which are for women's issues.

This company, in addition to some of the other products, they made the Obtryx sling. They made it to treat what's called stress urinary incontinence.

Now, the textbook definition of stress urinary incontinence is the uncontrollable leakage of urine during physical activities such as coughing, sneezing, lifting, laughing, or exercising.

This condition primarily afflicts women, and it primarily afflicts women who have had children. And as you might suspect, as we all get older and as we age, we tend to get wrinkles under the eyes, gray hair, our bellies get bigger.

Well, your internal organs age just like the outside of you does. Sometimes your body parts internally droop. Sometimes you lose some of the support that you have in different body parts.

Well, what stress urinary incontinence is, it is the

loss of adequate support from the urethra that's right above the bladder. And, so, when that support is lost, as women age, the urethra doesn't close properly and you get leakage.

It's an embarrassing condition. It can be uncomfortable. But there are many effective ways to treat this condition. Exercise is one such option that women have available to them. Medications are available. Pads or diapers are available. And there are also surgical options. And there are many different types of surgical options that can treat this condition.

Boston Scientific made the Obtryx sling. Each of my clients has the Obtryx sling. And there are essentially four component parts to the Obtryx sling. And that's the kit you're looking at there.

There are these two big hook-like devices. These are called trocars. And you're going to hear a lot about trocars throughout the course of the trial.

There's also this mesh. And you're going to hear a lot about the mesh. And essentially -- I'm no doctor. You're going to hear from some smart medical people that are going to tell you exactly how this product works. But just from a conceptual standpoint, the idea behind the mesh is that it is inserted transvaginally with these hooks and that it is supposed to reinforce and provide support for the urethra that's been lost over time. And, so, the urethra will close

and the leakage will stop.

Now, this product is supposed to be put in once, once. It's a permanent implant. It's intended to be in the body for life. It's intended to fix the problem for life.

And this mesh here -- and not all this mesh goes in. But essentially what they do is once they get it inside, they clip it. And there's a portion there that's used to support the urethra.

So, what went wrong? In each of these cases, this product didn't work. In each of these cases, each of my clients has had to have a second or third surgery to fix the problems caused by this product or have it removed.

And the consequences for each of my clients is severe and life-long. And, most importantly, the consequences were avoidable. They were avoidable if this company would have done its job.

This is really a case about lost trust. My clients trusted that they were getting a product that had been tested and was safe. That may seem illogical. Right? A company makes a product that's going to be put in your body for life. You would expect it to be tested in humans and establish it's safe before they started selling it to women.

My clients trusted that they were being told the truth about the dangers of this product and what this company really knew about the product. In both cases, this company

failed my clients.

You're going to hear over the course of this trial that they never tested this product in humans to make sure it was safe before they began selling it. It is undisputed. There will be no lawyer, no witness, no expert to come in from their side to say, "We did human testing on this product."

You're going to hear that they didn't give the full truth about the dangers of this product and what they really knew about the properties that comprise this product.

As you go through the evidence over the course of this trial, there are a couple of guiding principles that will help you evaluate the evidence. Now, these aren't controversial in any respect. You're not going to hear Boston Scientific's lawyers get up and say they don't agree with these rules. But these rules will help guide you as you evaluate the evidence that's presented to you over the course of this trial.

First rule: It's Boston Scientific's responsibility to make sure its products are safe for women. You're going to hear their employees say, "Yes, it's our responsibility. It's our product. It's our profits. And it's our responsibility to make sure they're safe before they begin selling them."

The second rule: It is Boston Scientific's responsibility to adequately warn physicians about the risks that are known or knowable about their products. That makes

sense too. Right?

You have doctors that are using this, surgeons that are using this product all over the country and they've got choices. They can choose other products. And it's Boston's responsibility to make sure these doctors are making informed decisions for their patients so that they have good outcomes.

So, how does a company like Boston Scientific warn? There are a number of different ways, but the principal way is with the Directions for Use. And I said there were four component parts to this Obtryx sling kit, and those are three. The fourth is the instruction manual. And this accompanies every product that's sold to surgeons.

And it's used primarily by surgeons for a couple of things. One, it tells them how to use the product. How do I use it safely?

And, second, and most important, it tells about the dangers associated with this product. It tells them about what does this company know that might be useful to a physician in making a decision about a product.

At the end of the day, the goal of this Directions for Use is to allow a doctor and a patient to have an honest conversation about choices because at the end of the day when you go into a doctor's office and you have to have a permanent implant, you want to have an honest conversation. You want to know the full truth so that if you make a decision knowing the

full truth and something bad happens, we're not here.

But if you're not told the full truth, if you're not given all of the information, the doctor and patient can't have an honest conversation. They can't choose which product is best for this particular patient.

We've all seen these shows *CSI*, *Crime Scene Investigation*. *Cold Case* is another one. And there are a lot of things about those shows that aren't really realistic. But there's a couple of things that are really, really important that happen that are relevant here.

And take *Cold Case*, for instance. *Cold Case* is that show where they're investigating cases that occurred years and years ago. And what happens at the beginning of every one of those shows? You see detectives going out of the evidence room and getting boxes and boxes of documents and witness statements, documents that were created at the time the events were occurring.

And from there, what they do is they put together a story. They figure out what the witnesses saw, what they heard, what they did, the decisions they made. They get to see documents that were created at the time the events were unfolding, and they put together the truth. They figure out what happened.

Well, your investigation in this case is no different. You're going to see different types of evidence

presented to you over the course of this trial. You're going to get to see testimony from the Boston Scientific employees, the people that were there that were making the decisions to test or not test, that were making the decisions what to include in the Directions for Use. You're going to get to see the internal documents that were created as these events were unfolding. And these documents and these employees are going to lead you to the truth.

There is no more important evidence in this case than those two things. The only people that really know the truth are the people that were there and the documents that were created at the time the events were unfolding.

Now, you're also going to hear from medical witnesses as well as doctors. They're going to talk to you about these ladies' injuries. You're also going to hear from experts. I've got experts. They've got experts. I hope you find my experts helpful. I think that in cases like this experts can be helpful on certain types of issues, and I hope you find mine credible. But at the end of the day, it is the employees that are going to tell us what the truth is.

Now, Rob Adams, my opposing counsel for Boston Scientific, we've been working on this case for two or three years together and his team. You're going to like him. I like him. But he was hired about seven years too late to fix a problem that's not fixable.

You're going to hear that from this company's perspective it's about winning. Remember that phrase. It's about winning. You're going to hear that when this product first came on the market, it was about winning and gaining market share and not about safety. In this courtroom for this company it's about winning, irrespective of the truth.

At the end of the day, though, when you push aside the lawyers, when you push aside the experts that we've hired, and you want to know the truth, you're going to hear it from Boston Scientific's employees' lips. These guys are going to tell you the truth.

And these guys just aren't low-level employees by any means. These are, these are at the top of the chain of command; Vice President of Regulatory Affairs, Vice President of Global Marketing, Vice President of Research and Development. You're hearing it from the bigwigs. Listen to their admissions. Listen to what they admit to. Listen to what they knew and the decisions that they made.

Now, the Judge at some point in this trial may talk to you about credibility. And it's your job to judge credibility; credibility of the witnesses, credibility of the evidence, my credibility. I hope over the course of this trial you find me credible, you find us credible.

But at the end of the day when you're listening to the lawyers argue, when you're listening to experts that have

been hired by the lawyers state their opinions, compare it to what the employees admit to and then listen to their arguments.

Are my arguments consistent with what they're going to tell you? Are my arguments -- are their arguments consistent or inconsistent with what you're going to hear?

Now, over the course of this trial you're going to be asked to answer three essential questions. And the Judge just summarized them for you.

The first is: Did Boston Scientific give physicians adequate warnings about the known dangers and those dangers which were knowable? Did they allow the physicians in these cases to make informed decisions? That's the first question.

Second question: Was the Obtryx sling defective? Was it made to be in humans? Remember that mesh. You're going to hear a lot about the mesh. Was the mesh fit to be in humans? You're going to have to answer the question.

And, last, the question you're going to have to answer is: How did these women suffer? What is their life today like? What have they been through over the course of the last five, six, seven years?

You remember I told you about that first responsibility. Make sure your products are safe. You're going to hear from Evan Brasington. He's the Vice President of Global Marketing.

Now, Mr. Brasington is going to tell you that when you introduce new products for sale, they need to be supported by reliable research. He's going to tell you that. That's common sense. But he's going to say, "Yeah, when you introduce a new product, it needs to be supported by science so people are safe."

Then you're going to hear from Rob Miragliuolo, the Vice President of Regulatory Affairs. He's going to say, "Even though we knew that, we did no human studies on this product prior to selling it."

You're also going to -- you may ask yourself, "Well, how in the heck -- how can a company make a product and ensure that it's safe with no human testing?" It can't. They know what the rules are.

Evan Brasington is going to tell you, "The rule is we've got to make safe products and we've got to have solid research." But they broke their own rules.

You're also going to hear from a gentleman named Charles Smith. He's the Director of Development. And you're going to hear from Charles Smith that in January of 2004, the people who make this mesh, Chevron Phillips, you're going to hear, make the mesh that go under that supports the urethra, that Chevron Phillips who was selling the resin to them, the little plastic pellets you're going to hear that ultimately are manufactured into this mesh product, you're going to hear

from Charles Smith that in January of 2004 Chevron Phillips said, "Don't use this product for permanent implantation in the human body."

He's going to tell you again in 2007 they told him the same thing. So, before they began selling this product, you're going to hear from their lips that, "We were told not to sell it." And even with that knowledge, they did no human testing.

You're also going to hear from a lady named Doreen Rao who was one of the principal engineers on the mesh project that became the Obtryx sling. You're going to hear from her live, and I believe you'll hear from her tomorrow.

She's going to say, "While we didn't do human testing, we did some other testing in the laboratory." And they did. But you're also going to hear that some of that laboratory testing failed. And, yet, they didn't follow up with human testing.

And, finally, you're going to hear from a gentleman named Alex Robbins. And you're going to hear that Mr. Robbins is involved in training key opinion leaders or doctors, training these doctors to go out and promote Boston Scientific's products.

You're going to hear that Mr. Robbins trains sales reps nationally. And you're going to hear that the global training manager for this company sought out his advice on a

study that the company had done that didn't turn out well.

And you're going to hear from Mr. Robbins in his e-mail that he said, "Don't send it to physicians. This won't help us selling our product."

Boston may argue that, "Listen, guys, there was plenty of testing on mid-urethral slings in humans." And you'll hear over the course of trial that the Obtryx sling is part of a group of slings that other companies make called mid-urethral slings. And you'll hear that there's some different versions of those. And they're going to say, "Well, gosh, we have tons and tons of studies on other products." Not on this product.

Boston Scientific made specific design changes that were different, made it different from any other product on the market, and they did no human testing.

You're going to hear evidence that they were given a new warning before this product was ever sold and still did no human testing.

Testing on other products done by other companies can't establish that this product is safe because it was different.

I've seen Boston Scientific use this slide and argue that, "Listen, look at all the studies that were done on Obtryx. Look at all these Obtryx studies that were done."

Start in 2006 and look at -- and you'll see what

these names are. These names are -- typically, studies are done by a bunch of different scientists. And, so, what we typically do is we refer to a study by the last -- the first scientist's last name.

So, if you look, for instance, in 2008 Gamble. That's called the Gamble study because that's the first scientist. And you may hear them say, "Look at all these studies that were done."

I'll just say this about this slide for now. Remember it. Remember this slide. I challenge Boston Scientific to put this slide up and suggest to you that these are all --

MR. ADAMS: Objection, Your Honor. This is argument. This is not talking about evidence.

THE COURT: The objection to that portion of your statement that began with "challenge" is sustained, Mr. Love.

MR. LOVE: Okay, sure. Thank you, Your Honor.

THE COURT: Yes, sir.

MR. LOVE: Now, with respect to this slide, if it's suggested in evidence that these Obtryx studies established that the product is safe, there's going to be fireworks because it's not the truth.

The truth is it's not until 2009, five years after this product is made available for sale, that this company does its first study, its first randomized controlled trial in

humans. And it's called the Ross study. The first study this company does five years after it begins to sell it to humans is the Ross study. And the results of the Ross study are disastrous.

Dr. Sue Ross was the lead author in this particular study. You'll hear that in evidence that she is a paid consultant for this company; that she was hand-picked by Boston Scientific to perform this study. And you'll hear that the study was comparing the Obtryx sling versus another sling called the TVT Advantage. So, they were comparing head-to-head which one's better, the TVT or the Obtryx.

And this is the last sentence in her study. This is what she tells the reader. "Until long-term studies are done, until long-term follow-up is available, the TVT should remain the mid-urethral sling procedure of choice."

So, Boston finally gets around to doing its own study and their own consultants say, "Don't use the Obtryx."

The rules say it is Boston Scientific's responsibility to warn. Here's the tragedy. Three of my clients had their surgery after this study was published.

Here's the other tragedy. Boston Scientific never updated the Directions for Use to make sure that this information was in this Directions for Use so that doctors could sit down with their patients and have honest conversations, so that they could make informed decisions, so

that a patient can sit down and that the doctor can say, "Listen, we've now got study results for the Obtryx. We've got one product that has been tested and it seems relatively safe. And then we've also got the Obtryx. But the Obtryx, however, you know, the scientist that did it recommends to use a different product. So, let's make an informed decision and a decision that's best for you."

That decision was taken away from my clients. Think about the conversation they could have had if they had known the truth.

Now, Boston may argue that, "Listen, we did biocompatibility testing. We did bench testing." You'll hear about bench testing. Here's the problem. You can't establish that a product is safe in humans by doing just this testing. This is the first step in a long line of testing that has to be done when you're making products that are going to be permanently implanted in the human body.

You're going to hear from Doreen Rao who was in charge of some of that bench testing. And she's going to say some of those tests failed.

You're going to hear from Rob Miragliuolo, the Vice President of Regulatory Affairs, say, "Listen, we know that you've got to test in the environment where the product is going to be used." Right? Makes sense. If you're going to permanently implant it in the pelvic region of a woman, you've

got to test it there. You've got to make sure it's going to work and it's not going to hurt people. They failed.

I mentioned earlier that Boston Scientific made a number of different products for women. And they did. One such product was a Pinnacle product. And it's used to treat a woman's issues as well. It's also transvaginally inserted. Just like the Obtryx sling, it didn't have any human testing done before it was made available for sale.

MR. ADAMS: Objection, Your Honor, with respect to the Pinnacle.

THE COURT: Counsel, come to the bench here briefly, please.

(The following occurred at sidebar.)

THE COURT: If I remember correctly, Judge Goodwin has not made a ruling on the admissibility of the Pinnacle. Am I correct about that?

MR. ADAMS: That is correct. Pinnacle is a POP product, pelvic organ prolapse. This case is about SUI products. He's referred to a number of SUI products and I haven't objected. That's appropriate. Like he's referred to the TVT which is a Johnson & Johnson product. And -- but pelvic organ prolapse is a different product. So is the Pinnacle.

MR. LOVE: If I could, both of these products have the polypropylene mesh. And the reason why it's relevant and

I'll be able to establish and the evidence will show is that neither one of these products had testing. But this product -- actually, Boston made a decision to actually warn physicians that they had no testing. So, they knew how to warn. They just chose not to.

THE COURT: At this juncture, tell me if I'm correct or not in my memory as to the status of the Judge's rulings with regard to the admissibility of the Pinnacle.

MR. LOVE: He has not ruled.

THE COURT: Then I have ruled that that should not come in in opening statements. I sustain the objection, preserving the plaintiffs' objection and exception.

MR. ADAMS: Your Honor, would you inform the jury that the objection is sustained so they know to disregard it?

THE COURT: Yes, sir.

MR. LOVE: And this --

Rob, just real quick.

This doesn't preclude our ability to lay a foundation during trial and establish it.

THE COURT: No. My understanding, Mr. Love, from my review of those motions is that that issue is outstanding because the Judge wanted to see the context in which it came in. I understand what you're proposing. But since it hasn't been ruled on at this juncture, I'm going to preclude it in opening as I stated on Friday.

MR. LOVE: Thank you, Your Honor.

(Sidebar concluded.)

THE COURT: Ladies and gentlemen of the jury, I have sustained the objection as to the Pinnacle and, therefore, you are to disregard any argument in reference to that.

MR. LOVE: May I proceed, Your Honor?

THE COURT: Yes, sir.

MR. LOVE: Okay. And what you're going to see over the course of this trial is you're going to see this Directions for Use quite a bit. And that's the Obtryx Directions for Use and this is it. And this is the book that contains the information that allows doctors to use their products safely.

And as the evidence will establish, Boston Scientific was told not to use this product for permanent implantation in humans. And it will establish that they never did any testing to establish that the product was safe and effective.

Unfortunately for my clients and the physicians who performed these surgeries, none of this information was included in this Directions for Use. And had the information been included, the warning would have looked something like this, and the warning would have told the doctor this information:

"The safety and effectiveness of the Obtryx sling compared to conventional surgical repair for stress urinary

incontinence has not been demonstrated in randomized controlled trials," because that's the truth.

"We've been told by Chevron Phillips not to use this for permanent implantation in humans." It's the truth.

Then the surgeons involved in this case could have sat down with each one of my clients and had that discussion and made an informed choice. And if they chose to go forward knowing this, great. They would have made an informed decision and we wouldn't be here.

Remember the Ross study that you're going to hear about. You're going to also hear about a study called the Cholhan study. After the Ross study was published, Boston Scientific chose not to put this information in the Directions for Use. If they would have, something like this should have gone in: "That based upon human clinical trials recently completed by Boston Scientific, we recommend physicians continue to use the TVT as the mid-urethral sling of choice."

You remember Dr. Ross. That's the conclusion she came to. Their paid consultant, that's her conclusion. Doctors aren't made aware.

Now, you may see Boston Scientific show you this, so I wanted to point it out for you. This is also in the Directions for Use and it's call the potential complications section. And what this does is it lists potential complications that can occur.

And what Boston may argue is, "Hey, look at all the stuff we did warn about. We warned about inflammation, pain, infection, erosion, foreign body response, vaginal discharge. We gave the doctors a lot of information. Isn't that good enough?"

And the answer is absolutely not. You know why? This information isn't based upon studies done on the Obtryx sling. This information is based upon studies done on other products. This is actually more misleading than putting nothing at all.

MR. ADAMS: Objection, Your Honor. This is argument again.

THE COURT: The objection as to it being misleading, or more misleading, counsel, that phrasing I'm going to sustain the objection.

MR. LOVE: Sure. Fair enough. Thank you, Your Honor.

What you will learn through the evidence is that there were no human studies done on the Obtryx sling. And, so, they couldn't have put any warning in. If they were being truthful and if they were being accurate in the information that they were putting in, they would have said something like this: "Boston Scientific does not know what complications are associated with the Obtryx sling as it has never been tested in humans. However, different products made by other

manufacturers to treat stress urinary incontinence have reported the following complications in humans."

So, at least at that point the surgeons and my clients could have sat down and said, "Listen, we're not sure what problems are associated with this particular product, but here's what other products made by other manufacturers have reported."

The second question you're going to have to answer is: Was the Obtryx sling defective? You heard the Judge. That's one of our claims. Was it safe to use in humans?

And rather than going through all the evidence again, you're going to see that they were told not to use it in humans, that they made changes to the product that made it different from any other product and never tested it.

You're going to hear about the Ross study. What you'll also hear, the evidence will establish, that if the Ross study is 2009, the Cholhan study is 2010, both of these studies are Boston Scientific. They're the first and second studies this company did.

And what you're going to hear is that had they done these studies initially, we wouldn't be here because one of the studies says, "Use a different product." The other study says there may be as high as a 24 percent rate of pain during sex, dyspareunia. If they had done the research they were supposed to, they would have determined that the product was

defective from the get-go.

The last question you're going to have to answer: How have the plaintiffs suffered in this case?

And you're going to get to meet Ms. Tyree, Ms. Wilson, Ms. Campbell and Ms. Blankenship. You're going to get to learn the stories and their stories and what they've been through over the course of the last several years. And you're going to meet each of them.

And you're going to find out that each of them are from different walks of life, different backgrounds, different socioeconomic classes, different political beliefs. But they have a few things in common. They're your neighbors. They're from West Virginia. They all have this product implanted in them, or did have it implanted in them.

And there's one more thing they have in common. They're all human beings and they deserve to be treated with dignity and fairness. They all deserve to be told the truth.

And Boston took that away from them. Boston took away their right to choose a different product, to seek a different path because they didn't tell them the whole truth; to choose a product that had actually been tested in humans.

They have one last thing in common. Every one of my clients has had this product removed or revised in surgery because of the problems this product has caused and the problems it will cause for the rest of their lives, all four.

Now, Boston is never going to acknowledge that they're responsible. They're not going to step up to the plate and say, you know, "We're responsible for --"

MR. ADAMS: Objection, Your Honor. Again, this is argument. This is not a discussion of evidence.

THE COURT: Mr. Love, any response to that objection?

MR. LOVE: Thank you, Your Honor.

THE COURT: Any response to that objection?

MR. LOVE: Oh, I was laying out what the evidence was going to show. I don't believe that the evidence will show that this company is going to take responsibility for their conduct.

THE COURT: I think that is appropriate wording for opening statement, counsel.

MR. LOVE: Thank you, Your Honor.

I don't think they're going to take responsibility for their conduct. I don't think the evidence will show that they are. They'll give you reasons why. They may blame the surgeons. They may blame my clients. They may blame everyone. But they're not going to look at themselves in the mirror just like they're going to say, "Well, we warned about a lot of stuff, but you're right. Maybe we didn't warn about everything."

All four have had this product removed or revised.

My clients' journey. You're going to hear about

their journey from the time they had it implanted through their first, second, or third surgeries. Each of these women are at a different stage of a painful journey. And this isn't one of those fun journeys. It's not a vacation by any means. It's a journey filled with uncertainty, with pain, with future medical care, a journey that none of these women deserve.

Ms. Blankenship you're going to hear had her Obtryx removed, or at least a part of it. And she's had a third surgery. Now her problem is actually fixed and she's doing better, not great.

Ms. Tyree, on the other hand, had the Obtryx removed. And you're going to hear that, as you might suspect, she's scared about having anymore surgeries.

All different, all the same product, all on a journey, just at different stages. But this is what they get to look forward to the rest of their lives. All of these women have experienced pain, intimacy issues with the ones they love most, medical care, reoccurrence of their stress urinary incontinence. And the tragedy is it all could have been avoided if this company would have simply done its job.

Now, I'm not here and my colleagues aren't here and my clients are not here today to tell you that every problem they have is because of this sling. I'm not going to suggest it. We're not going to say it because it's not the truth. But just because they had some problems before their surgery

doesn't give this company the right to make some of them worse and create new ones.

This is a big case with big damages and very bad, big decisions made by this company. Now, we've worked real hard over the last four or five months to put this case together as efficiently as we can, and we're going to bring you the evidence so you can complete your investigation. We're not going to waste your time.

On behalf of myself and my clients and my colleagues here, I appreciate your time this morning. We look forward to working with you over the course of the next couple weeks. Thank you.

THE COURT: Counsel, Mr. Adams.

MR. ADAMS: Thank you, Your Honor.

May it please the Court, Your Honor.

THE COURT: Yes, sir.

MR. ADAMS: Ladies and gentlemen, this is a real-life story about women seeking options for a life-altering condition of stress urinary incontinence.

We all face conditions in our lives. And when they're serious conditions or life-altering conditions, we go to our doctors, and we talk with our doctors and our doctors counsel us. And we have a choice to make. You can live with the condition or you can do something about it. And the doctors, when they tell you you can do something about it,

they describe the risks. And here the only option available for these ladies was a surgical option.

Now, you've just heard a very nice discussion from Mr. Love. But one thing that was absent, starkly absent was any discussion about the treating physicians, what they knew, what these women's conditions were, and why they chose the Obtryx. This case is really a story about women seeking options for a life-altering condition.

Now, the women in this case, there are four of them. And, actually, two of the women went to the same treating doctor. That's Dr. Bhanot. So, there's really only three doctors that we're talking about in this case. There's Dr. Bhanot, Dr. Lassere, and Dr. Luby.

And the central question that you have to decide is why is it that all three of these doctors located nearby, right here in West Virginia, all three of these doctors who care about their patients, who read up on the medical literature, who stay current and who have been in the practice of medicine for a combined number of 71 years, why did they all choose this product? That's the central issue in this case.

And, ladies and gentlemen, they all chose the Obtryx because their experience, their clinical experience in treating other women showed to them that this product is safe and it's effective. If it wasn't safe and effective, based

upon their treatment of other women, they wouldn't have recommended it to these women.

Again, these doctors -- Dr. Bhanot you didn't hear anything about in the opening statement of the plaintiffs, 28 years of clinical experience.

Dr. Lassere, 22 years of clinical experience.

Dr. Luby, 23 years of clinical experience.

They chose the Obtryx based upon the medical literature that they routinely review, and they chose the Obtryx based upon their clinical experience.

Now, what does clinical experience mean? Clinical experience means that these doctors had used these products well in advance of the time that they used them with the plaintiffs at issue and they had good results.

Boston Scientific sells products to hospitals, and doctors can choose or not to choose -- not, not use the products. At any time if these doctors felt that that product was unsafe, if they were getting bad results with any of the other patients that they treated, they could simply go to another product. But they didn't do that. They chose the Obtryx.

Let's focus on Dr. Bhanot. Dr. Bhanot, you're going to hear his -- you may hear his deposition or he may come here live. And a deposition is just like live testimony. Here's what Dr. Bhanot knew about the Obtryx and his prior knowledge.

He went to medical school in 19 -- graduated in 1972. He's a board certified urologist. He, like other doctors, engage in continuing legal education -- not legal education, medical education about products. They also belong to professional organizations. You're going to hear about professional organizations of doctors like these doctors at issue.

And all of these doctors are not internists. They're specialty doctors who treat the condition of stress urinary incontinence. That is the majority of their practice. And Dr. Bhanot kept up on the medical literature. He goes to medical conferences. And he had personal experience with not only the Obtryx, but other types of what are called mid-urethral slings.

And the Obtryx is not the only product out there. So, when Mr. Love was talking about the Obtryx and showing these devices, there's a long history that I'm going to tell you about of other devices that have been used in women since the 1990s.

Dr. Bhanot also went to various training programs to learn from different companies and different experts about how to safely use these product.

Let's talk about his clinical experience. He performed nearly 700 -- has performed nearly 700 mid-urethral surgeries. And most of those surgeries involve the Obtryx.

At least 90 percent of his patients substantially improved after the surgery. And he's had a very low complication rate.

It goes back to what I told you, talked about earlier, that when we go to our doctors and our doctors give us options, we have to weigh the risks of engaging in an option like surgery versus the benefit of having that condition resolved.

That's the issue that all of these women and all of the doctors had to judge and had to go through. You weigh the risks of the surgery versus the benefit of having the condition eliminated or resolved.

And based on Dr. Bhanot's experience, at least 90 percent of his patients substantially improved after the surgery. And he will tell you that he had a very low complication rate. Again, if he didn't believe that this product was effective, he would not have recommended it to two of the women in this case.

Let's talk about his experience with other SUI treatments. Now, we've been talking about stress urinary incontinence. And there's really going to be no dispute in this case that all four of these ladies, all four of these ladies have severe stress urinary incontinence.

Mr. Love talked about other options that were available like exercises. They're called Kegel exercises. He mentioned some other different types of therapies. But for

these women, their SUI was severe enough that those were not options. Really, the only thing that was going to resolve their condition -- and you'll hear this from the doctors. The only thing that was going to resolve this condition was surgery.

And, in fact, Dr. Bhanot will tell you that the Kegel exercises rarely work. There's also some devices that are actually bulking agents which can be injected. And they're ineffective.

And then there's some other surgical procedures. There's a procedure that you're going to hear about called the MMK. That's where an incision is made in the abdomen. There's a procedure called the Burch procedure. And that also has a lot of complications associated with it according to Dr. Bhanot.

And Dr. Bhanot will tell you that the success rate of mid-urethral slings is superior to the other procedures. These doctors don't just practice in a vacuum. So, when Mr. Love was talking about Boston Scientific did this and Boston Scientific did that, we didn't tell them about a study, I want you to keep in mind the studies that he talked about, Ross and Cholhan, are published in the literature. Doctors read the literature. Boston Scientific isn't withholding studies. They're actually published so doctors can read it.

Let's talk about Dr. Lassere's knowledge. Dr.

Lassere went to medical school, board certified. He does the same type of continuing education. He keeps up on the medical literature. He goes to medical conferences. And he had personal experience with mesh and he went to different training programs.

His experience with the Obtryx -- he actually started using mid-urethral slings back in the late 1990s. I'm going to talk more about the history. But, again, Boston Scientific didn't come up with the idea of using polypropylene mesh to treat women with stress urinary incontinence.

You're actually going to find out that it was surgeons who took the concept of using polypropylene mesh that was actually originally used in hernia surgeries. They took that concept and they cut strips of mesh in order to place it underneath the urethra.

So, medical device companies, and certainly not Boston Scientific, didn't come up with the idea. It was the surgeons who came up with the idea.

So, back in the 1990s Dr. Lassere first started using mid-urethral slings. And he changed to the Obtryx in about 2007, 2008. He's performed approximately 50 Obtryx surgeries, probably more by now. And he's had a positive clinical experience with the Obtryx.

And the erosion rate -- and erosion, we'll talk about that later, but that's one of the complications that you're

going to hear about in this case. His erosion rate for all of his patients is one percent or less.

So, why does he use the Obtryx and mid-urethral slings over the other options that I talked to you about? He will tell you that the mid-urethral sling is superior to the Burch procedure.

Now, I've been using the term "mid-urethral sling." The Obtryx is a mid-urethral sling. The plaintiffs will not dispute that. You're going to find out that the classification of mid-urethral slings, they basically all involve the similar concept of using a thin strip, thin light strip of polypropylene mesh to place it transvaginally underneath the urethra to provide a hammock. And that hammock -- basically, when a woman coughs or sneezes, it prevents the leakage of urine.

Let's talk about Dr. Luby's knowledge. Again, all of these gentlemen are local practitioners. Dr. Luby, medical school in 1990, board certified OB/GYN. He's done continuing legal education. He's a member of all the major organizations that you're going to hear about. He keeps up on the medical literature and he goes to conferences. And he talks with other doctors. That's another important thing.

Again, these doctors don't just practice in a vacuum. They go to meetings where they talk with other doctors. They go to ground, grand rounds which are actually meetings within

their hospital where they talk with other people that practice in their area about devices, surgical options, and what people are using.

Dr. Luby used the Obtryx and he's performed approximately 200 Obtryx surgeries. He says that mid-urethral, mid-urethral slings like the Obtryx are the gold standard for the treatment of stress urinary incontinence. He's had a 95 to 99 percent success rate.

His complications -- he's really had no complaints. And Ms. Tyree was one of his few patients who had complaints about dyspareunia.

Dr. Luby had similar experience with the other older treatments; said that Kegel exercises are rarely effective. The Burch procedure is more invasive. And we'll talk a little bit about that. I've already referenced the fact that the Burch procedure and what's called the MMK procedure involve a cut in the abdomen. Women have to spend one to two days in the hospital. And their recovery time is much longer.

There's also things such as a native tissue repair. He says that in his practice that is reserved as a last resort for patients. And then, again, I mentioned bulking agents. He said bulking agents are less effective than mid-urethral slings. So, I want you to think about the clinical experience of these doctors.

Now, Mr. Love referred to two different articles and

I'll talk about those later. But let's just consider the experience of these doctors as if it was an article in and of itself.

Their experience, if you combine it all together, they've placed approximately 550 Obtryx slings and they've had very low complication rates, 90 percent success, 95 percent success. And all of them believe that the mid-urethral sling like the Obtryx are the gold standard or the standard of care to treat SUI or stress urinary incontinence.

Again, these doctors are on the ground, boots on the ground practicing every day doing these procedures. And they see whether their patients experience any type of complications.

At any point in time if they had problems with the Obtryx, they would have done what they should do for their patients and used another product. But they didn't. They continued to use the product and they've done what other doctors do out in practicing medicine.

And it goes back to what I said right from the start. When you have an option presented to you about how to get rid of a life-altering condition, it involves a balancing of the risks of a procedure like a Burch procedure or an MMK or using a mid-urethral sling. What are the risks versus the benefits.

The benefits are that the conditions, problems can be eliminated or substantially reduced. And that's what doctors

do every single day when they recommend procedures, products, drugs to us when we have conditions.

You know what. Everything has risks. If we take -- if we have some type of condition and we take a drug, that drug, if you open up the pill bottle or get it from your pharmacy, it's got risks associated with it. If you undergo any type of surgery, it has risks associated with it. It involves a trade-off.

And the trade-off that patients like these women and us when we have different types of operations, the trade-offs are: Are the risks outweighed by the benefits, or do the benefits greatly exceed the risks?

And for these doctors that we've talked about, you're not going to hear from their other patients. You're just hearing from four people. But think about it. 550 women at least were treated by these doctors. 90 to 95 percent of these women had successful outcomes. You won't hear from them.

So, Mr. Love is right. This case is going to come down to really three questions. And I liked his, his reference to the *CSI* and the *Cold Case* because you know what. This case is about when you're examining the evidence, you're looking at it without passion, without prejudice. And you're looking at it in a scientific way. You're looking at, well, what makes sense?

And one thing that's going to be important is -- and you've already saw it. Mr. Love showed a picture of Boston, the city of Boston. He talked about Boston Scientific. Well, Boston Scientific is actually located about 45 miles outside of Boston. And given the traffic, it takes about an hour and a half. It's like being located in Huntington. And it's located in a small, somewhat, almost a rural area. It's outside of a little town called Marlborough.

And when you're examining the evidence, you need to keep in mind that Boston Scientific is composed of people. And those people under the law are entitled to the same consideration as the four nice ladies who Mr. Love represents. So, you shouldn't let passion or prejudice or any bad feelings about a corporation enter into this process. That's not what it's about.

It's about looking at the evidence scientifically. And you're going to look at three questions. Is the Obtryx safe and effective? Has Boston Scientific adequately warned doctors about the product? And are the injuries that the plaintiffs have caused by a defect in the Obtryx?

So, let me give you a road map of what I'm going to talk about for the remainder of our discussion.

First, we're going to talk a little bit about the disease of stress urinary incontinence. Then I'm going to talk about the treatments associated with that. And we've

already talked a little bit about it. And then I'm going to talk about the Obtryx and the plaintiffs.

So, let's begin. Now, Mr. Love has talked to you basically about stress urinary incontinence, but I want you to understand exactly how it works.

Here is the normal female anatomy. And you can see the urethra. And most of our discussion is going to be focused on the urethra. And Mr. Love is right. Due to age, gravity, and just the natural processes of our bodies when we get older, especially women who have children, they develop a loosening of the pelvic floor that allows the urethra to get in the position to where it can leak urine.

And there's no dispute in this case that stress, severe stress urinary incontinence is a life-altering condition. You're going to hear about the horrible issues that these women had to deal with. And no woman should have to deal with that.

Stress urinary incontinence occurs when pressure either from coughing, sneezing, lifting, and doing other things, when pressure is placed inside the body, it moves to the bladder and then it causes the urine to leak out of the bladder.

And that pressure, at times it can get severe enough, and you're going to hear from the plaintiffs, that it can become severe enough that women are forced to wear adult

diapers. They have to change their clothes several times a day.

One of the ladies in the case talked about how she had to change her clothes four times a day. Women shouldn't have to live that way. And, in fact, stress urinary incontinence affects many women. There's estimates and there's scientific literature that 50 percent of women as they get older, especially women who have babies, they're going to have stress urinary incontinence.

And 30 percent of those women are going to need surgery. They're going to need surgery because it's severe stress urinary incontinence. It goes back to the options. Other options that are not surgical options weren't available to these ladies. And their doctors knew that. Otherwise, they would have chose some other treatment. But they chose the surgical option.

So, when you look at the options, there's nonsurgical and surgical. These ladies had to have a surgical option. When you get into the field of surgical options, you're going to hear about traditional procedures. And these procedures have been around a long time. There's a Burch procedure. There's another one called the MMK. And sometimes they refer to it as traditional or older procedures.

And then you're going to hear about mid-urethral slings. And, again, doctors came up with the idea of

mid-urethral slings. And it's really -- the story is fascinating. The story goes back to the 1950s when mesh first started to be used in hernias. And doctors talk -- surgeons talk about the efficacy of different products.

So, at some time after surgeons started using polypropylene mesh to treat hernias, later you're going to hear that in the '60s and the '70s doctors were custom cutting pieces of that same polypropylene mesh and using it to treat stress urinary incontinence. And, again, the Obtryx is a type of mid-urethral sling.

These are a list of the other older procedures, procedures that have been around for a long time. And then we have the mid-urethral sling which really started in the '70s, but manufacturers started making those products because surgeons were custom cutting it. There was a need for companies to make the products.

And you'll hear that the first company to do that was actually Johnson & Johnson, or a division of Johnson & Johnson in the 1990s.

The Burch procedure is an abdominal procedure. It involves a cut in a woman's stomach.

The MMK is abdominal. You're going to hear that there's other procedures that are abdominal surgeries.

There's actually an interesting surgery that's the use of a pubovaginal sling. That's where, again, you're

making an abdominal incision and you're actually taking cuts of a woman's skin or tissue and using that same tissue to create a sling. All of these procedures were rejected by the three doctors who treated these ladies.

Now, I want to talk about Ms. Campbell's SUI. And I'm not going to, not going to belabor this point. I don't think that even the plaintiffs are going to contest the fact that they all needed the surgical option. She talked about how she was asked questions. And we were entitled to take the depositions of these ladies before and find out about their condition.

And she talked about her condition. And we asked her, "On a scale of one to ten, how has this affected your quality of life?" She said, "At least a ten." And then I already discussed with you the other issues about basically she said she was leaking all over herself, having to change her clothes four to five times a day, missing social events.

Ms. Wilson also had severe SUI. She was spraying urine at the end of 2009 when she coughed, sneezed, lifted items, when she had sex.

And, again, ladies and gentlemen, when we discuss -- when Mr. Love and I discuss these issues, I want to make one thing perfectly clear. I agree with him that these are nice ladies. These are nice ladies. And we need to be respectful to their issues. And when we talk about the conditions, in no

way do either Mr. Love nor I mean any disrespect. But, frankly, that's what this case is about.

If this case was about the issue of whether they're nice people or whether you may have sympathy for them, you know what? There would be no reason for a trial. But it's not about that. It's about a search based upon the evidence to answer those three questions that I talked about earlier.

So, even though you may feel sympathetic to them, you need to set that aside. You know, there's a great quote from Oliver Wendell Holmes that -- he was one of the Supreme Court Justices. And he said sympathy is one of mankind's greatest human virtues, but it has no place in the courtroom.

So, when you look at this evidence, you need to judge it based upon the facts. And it's unquestionable that all of these women had severe SUI. Ms. Blankenship had to wear pads. Eventually she had to wear adult diapers. She had irritation from wet pads.

Ms. Tyree, again, severe SUI. She went to Dr. Luby because she didn't want to suffer anymore from the stress urinary incontinence problems.

Now, I want to talk to you about the Obtryx. As I said before, the Obtryx is a class of device called a mid-urethral sling. Boston Scientific didn't invent that device. Other companies invented the idea for the device. And I think you may have had the impression that somehow Boston

Scientific had created just this device and it sold it to these physicians and somehow duped them into using it. Well, that's not true. This device has been around -- the type of device has been around for a long time.

And you're going to hear about studies about how many different doctors, like the three doctors that I showed you before, how many different doctors use the same types of devices that involve polypropylene mesh placed transvaginally inside the vagina to anchor the urethra.

Here's a study -- and you're going to hear a lot about studies. Here's a study that is actually out of a journal, the *Female Urology Journal*, and it's entitled "Mid-Urethral Sling is the Dominant Procedure for Female Stress Urinary Incontinence."

And what the study did is it looked at doctors who were board certified. And it said they looked at a total of 6,355 urologists. And the conclusion of the study after they looked at and researched what these doctors were using to treat this condition, here's their conclusion."

"Mid-urethral slings have been widely adopted by urologists over the last decade. Increase in sling usage coincided with a drastic decline in traditional procedures, implying that the newer mid-urethral slings were replacing these traditional procedures for the treatment of female urinary incontinence."

And, ladies and gentlemen, that's what all these three treating physicians said. They don't do these other procedures. They use devices that are very similar to the Obtryx.

Here's also what the article said. It said, "The large increase in the use of sling procedures over the past decade, combined with the relatively stable number of periurethral injections, indicates that traditional repairs --" those are the repairs with the cuts to the abdomen. Sometimes you can do it laparoscopically. "Traditional repairs have almost entirely been replaced by mid-urethral sling procedures. Between 2003 and 2012, the number of traditional procedures fell from 784, or 17 percent, to just 56. One percent of the treating physicians do those repairs."

And this chart stands for that proposition. You can see at the top these are the traditional repairs that have decreased down to about one percent of the doctors.

So, these three doctors that we've been talking about that you didn't hear much about in opening statement, those three doctors, like the majority of doctors out in the world practicing in their specialty, offer the same type of device to their patients. And the Obtryx sling you're going to hear about is a device that is like all the other mid-urethral slings.

Now, there are two different types of approaches that are going to come up in this case. And I'm going to explain that to you in a minute.

The Obtryx is placed -- and you saw the trocars.

Mr. Love, do you have the trocar?

MR. LOVE: I do.

MR. ADAMS: Thank you. May I use that?

MR. LOVE: You may.

MR. ADAMS: Thank you.

The Obtryx sling is placed in a woman's body by the use of a trocar. And, ladies and gentlemen, frankly, you know what? When I looked at this -- when I looked at this for the first time, I was concerned about it. You know that? I'm not a surgeon and I looked at it and thought, wow, I've never seen a device like that. But these types of devices are common in surgery, and these doctors use these devices every single day.

And this is the piece of mesh -- and I want you to understand that this piece, this entire piece does not stay within a woman's body. The piece is trimmed off after it's placed in the body. It's placed in the body by making a cut underneath the urethra. And then the Obtryx -- those devices called the trocars go through. And this is called the obturator foramen. This is the pelvic. So, it goes through the obturator foramen on one side or the other and it's placed underneath the urethra.

And you're going to see that all of the mid-urethral slings involve the same type of procedure. There are some different techniques and there's also different placements that you're going to hear about. But that's basically how the device works.

So, here's a diagram showing you how the sling is placed. You can see that this is the pubic bone. And the sling is placed so that it actually provides a support or a hammock. I used that term before. It's a hammock to generally go underneath the urethra so if a woman coughs or sneezes or does other things, she doesn't leak urine.

We talked about the history of polypropylene mesh. And I told you about that really back before even this timeline, surgeons came up with the idea of taking polypropylene mesh that has been used in surgeries since the 1950s for hernia repairs. Smart doctors came up with a concept of cutting sheets of mesh into thin strips like this and then placing that transvaginally through the woman's vagina.

And then what happened is that medical device companies in working with physicians recognized that there was a need for devices that were already pre-cut and pre-made.

And the first company to come out with the first mid-urethral sling was Johnson & Johnson with the TVT in 1997. And the TVT involved the same type of mesh, polypropylene

mesh, but it was placed in a little bit different position and they had a different approach.

Then you'll see that there was another sling that came out from another company. And then you'll see that Boston Scientific came out with their first sling which was called the Boston Scientific Advantage sling in 2002.

So, again, you can see that five years before the TVT was already out on the marketplace, five years later Boston Scientific came out with their sling. And that's important because, again, Boston Scientific was able to observe the studies and the reports of the success of the TVT in the marketplace and the fact that there were very low complications and it was an effective surgery and Boston Scientific then came out with the Advantage and the Lynx.

Now, I've talked about the different approaches. These approaches -- the first three products that are on here involved the retropubic approach. The other approaches are transobturator approaches. You can see there was a MonArc sling, a TVT-O, and the Boston Scientific Obtryx.

Now, I'll explain what that means in a moment. But I wanted you to know that at the start all of these products use the same type of polypropylene mesh. But the first three products, including Boston Scientific's Advantage, was a retropubic approach. The next three products are what's call the transobturator approach.

Now, why did the transobturator approach come about? You're going to hear that there was a reduced incidence of bladder injuries in the procedure. And that's why there was another option advanced or put out in the marketplace called the transobturator approach.

Both of these options still remain available to surgeons. And surgeons are the ones who ultimately make the call as to whether they like one product versus another.

So, let's talk about the development of the mesh. Mr. Love talked about information that Boston Scientific knew about this product. Well, what we knew about polypropylene mesh was that polypropylene mesh had been around since the 1950s. We were able to -- the people at Boston Scientific were able to observe the success of the TVT and the fact that that was providing great benefit to women in the marketplace.

So, Boston Scientific when it created its first sling actually had an engineer named Doreen Rao research the issue on the mesh used by the TVT. And she went out and she did research and you're going to hear about that. And the original Advantage mesh which was first used in the Advantage and then later used in the Obtryx, it's the same mesh.

What did Boston Scientific do and task Doreen Rao to do? We tasked her to basically create the same type of mesh. And here's a photograph showing the Advantage mesh which is used in the Advantage product and the Obtryx product and the

TVT mesh. They're almost identical. And it's the same type of material, which is polypropylene. Again, polypropylene has been used in the body since the 1950s.

So, when you hear Mr. Love talk about Boston Scientific had these warning signs and Boston Scientific should not have used polypropylene, keep in mind that we fashioned our mesh, the Advantage mesh that, again, is used in the Obtryx to be just like the TVT.

Now, I talked about the two different approaches. Some products are retropubic. Those are the three products that I mentioned before. The TVT was the first one. Other products like the Obtryx are through the transobturator approach.

Now, there's risks and benefits associated with each product. It's like what I've said repeatedly. The transobturator approach, the benefit of that is there's a reduced incidence of perforation of the bladder in the procedure. Other doctors prefer retropubic. The doctors at issue here like the transobturator approach.

Here's a chart that shows -- and it's really going to be undisputed in this case. Polypropylene has been used in the body, different parts of the body for 55 years. It's not just used in hernias. It's used in chest walls. It's used in fingers. It's used in all sorts of different locations. And that's going to be undisputed in this case. But in this case

we're going to be focusing on the use of polypropylene specifically underneath the urethra. And, again, there's even incidents of the use of polypropylene in the head and the brain.

Now, I want to focus on Boston Scientific's history and use of the specific type of polypropylene at issue.

Now, Mr. Love spent a substantial amount of his opening statement talking about Boston Scientific didn't properly test the product, and Boston Scientific was told by the supplier of the polypropylene to not use this product in humans.

And you know what. I looked over and I saw that you were concerned. And you know what. You should be. You should be. And I'll tell you that Boston Scientific reacted immediately when it received that information. But what's interesting is the history about the information, about, "Do not use this in human bodies."

Now, Mr. Love didn't show you the document. It actually is a document that accompanied the polypropylene resin. Now, polypropylene resin is the raw ingredient that is actually spun into fibers and then woven into the mesh.

So, when he talks about this labeling that says "not for human use," or something to that effect -- and you'll see it later. It's called an MSDS sheet. What's important to note is that Boston Scientific was buying that polypropylene

mesh -- or buying the polypropylene pellets for use in its products since 1992.

Since 1992 we were buying the same exact type of polypropylene from a company called Phillips. It started with the mesh called the Trelex mesh which was used for hernia repairs. And then in 2002 we talked about the Boston Scientific's Advantage sling that came out. We were using the same type of polypropylene. And then in 2004 the Obtryx was introduced. And then later in 2008 we've come out with another sling.

What's important to note is that this same polypropylene pellets that were spun in the mesh, into the mesh has been used since 1992 in mesh placed inside the human body. And biocompatibility testing was done by Boston Scientific on this polypropylene. And it was established through testing.

It's not only established through testing. It's established through a history of use of polypropylene, the same exact polypropylene in the body since 1992 in Boston Scientific's products.

Now, this medical -- this MSDS that contained the language that Mr. Love talked about, it was not contained within any of the pellets or the raw material from 1992 all the way until 2004. So, from 1992 to 2004 this statement in what's call the MSDS sheet was never contained within the

material that was received from Phillips Sumika to Boston Scientific.

Now, in 2004 they added a statement saying, "Not for use in the human body." And, again, Boston Scientific when it got word of that statement was concerned about it and reacted immediately.

And what did we find out? We found out that there was no scientific basis and no studies -- nothing was done by this company to support its claim in 2004, years after it first started supplying us the same polypropylene pellets, that there was no scientific basis for that statement.

And you're going to hear in this case -- in fact, a gentleman from the company -- and we took the deposition of the corporation and we asked them to provide a representative who could talk on the issues as to whether there was a scientific basis for the statement. And you're going to hear the deposition of Mr. Frank Zakrzewski. He's going to say that that statement was not added based on any scientific testing. It was not added based upon any polypropylene data. And it was not added based upon any scientific or medical literature.

And, in fact, you're going to hear from Doreen Rao. Doreen Rao is -- and plaintiffs are going to call her tomorrow. She will tell you that after this change in the MSDS was received, she actually was told by people at Phillips

Sumika that the statement was put in for some type of legal reason. It was not put in for any type of medical -- not based on any type of medical or scientific basis.

Now, so, when you hear plaintiffs talk about this MSDS language, you're just going to hear plaintiffs' portion of the case. Keep in mind this will be a ten-day trial. And plaintiffs get to choose bits and pieces of evidence that they may show you in depositions that will be played to you or through statements of witnesses. Keep in mind that you need to have an open mind and wait for all of the evidence to come in for Boston Scientific.

And, again, it's going to be undisputed in this case that mid-urethral slings are really the gold standard for the use of doctors, and that the Obtryx device is in the same classification. And, again, it's the same basic principle using the same material.

You're going to see a lot of literature. This literature talks about the transobturator sling has become one of the most popular and effective surgical treatments for female stress urinary incontinence worldwide.

You're going to hear about position statements. Remember when I showed you the history of those doctors before and talked about the different societies that they belong to. All of the major societies of doctors who treat women, you're going to hear that they have come out with position statements

that are supportive of the use of polypropylene slings.

Here's a position statement from a group called AUGS. It says -- and AUGS is the American Urogynecological Society. And it's down here in the fine print. And there's another group called SUFU. You're going to hear about a bunch of different groups that doctors like the three doctors that are the main characters in our case belong to. And they care about their patients and they study products.

Here's the position statement from AUGS. It says, "The polypropylene mesh mid-urethral sling is the recognized worldwide standard of care for the surgical treatment of stress urinary incontinence. This procedure is safe, effective, and has improved the quality of life for millions of women."

Again, when you think about the doctors at issue, those three doctors that I've said have done 50 Obtryx procedures, they said that their success rate is 90 percent or more. You won't hear from the 90 percent of those patients who got a great benefit.

This group also talked about polypropylene material and said it's safe and effective for use as a surgical implant. Remember the diagram I showed you earlier. They say that this material is used in cardiovascular surgery, eye surgery, gynecology surgery. It's been used for more than five decades.

And then they say that, "As a knitted implant for the surgical treatment of stress urinary incontinence, macroporous, monofilament, lightweight polypropylene has demonstrated long-term durability, safety, and efficacy up to 17 years."

They go on to say, "It's one of the most extensively studied anti-incontinence procedures in history." And then they talk about how it's the standard of care. And, again, you'll hear the term "gold standard."

More than three million mid-urethral slings have been placed worldwide. So, it's not just our three doctors located in West Virginia here treating these nice ladies who use these products. These products are used worldwide. And the Obtryx is sold worldwide.

They say the procedure is probably the most important advancement in the treatment of stress urinary incontinence in the last 50 years. There's other organizations -- and I'm not going to take the time -- that also support these same devices. You're going to hear about studies. And the studies all conclude that these devices are safe and they are effective.

And really nobody in this courtroom and not the plaintiffs are going to dispute that mid-urethral slings like the Obtryx are the most studied procedure for incontinence. It's the most used treatment and they're the most effective

treatment and they're safe.

Now, so, what you heard Mr. Love talk about is, "Well, there's something different about the Obtryx. There's something different." Well, what's different about it?

He points to, again, this language that was within the pellets, the raw material, the MSDS. It changed. It changed because in 2004 for legal reasons they decided to put that language in there. They didn't do any type of testing. Boston Scientific had already done the testing. And they did more testing. And they found basically what they knew before, that polypropylene, and this specific polypropylene, was safe and effective.

So, what's different? Well, Mr. Love has talked about the Ross study and he talked about the Cholhan study. I, I can assure you of this. By the end of this case, you will be sick about hearing about studies. You know what? For every study that is going to be brought up, you're going to hear criticisms about the study.

The doctors, the three doctors at issue in this case, they all read the studies. They see the different doctors reach different conclusions. At the end of the day, that's why they rely upon their clinical experience.

Now, Mr. Love talked about Boston Scientific withheld these studies. You know what. That really doesn't make sense. If we were trying to do that, we didn't do a very good

job of it because these studies are published in the scientific literature. The Ross study is published in a urogynecology journal. It's available for doctors to read. Same with the Cholhan study.

An important part about it is that the Ross study and Cholhan, they do reach certain conclusions about the Obtryx. And you know what. The doctors -- like I said before, studies vary. But what you're going to find out in this case is that the overall majority of these studies conclude that the Obtryx device is safe and effective.

And, in fact, there's a recent study. It wasn't on Mr. Love's chart, but there's a recent study that just came out in 2014 by some doctors in Turkey that say that this device is safe and effective.

I put parentheses around, next to the titles of these different studies because you can see that the volume of patients who were involved in the studies varies from study to study.

And, again, there's going to be a great debate upon these studies. But at the end of the day, I believe these studies will show that the device is safe and effective.

This is the Tarcan study. That is the 2014 study that just came out. It was published online and says, "The aim of the study was to evaluate the safety and efficacy of the retropubic or transobturator TO mid-urethral sling."

Again, that's the Advantage, which is one of our products, was compared to the Obtryx. And the conclusion reached was that both devices are highly effective. And there is no significant difference between the retropubic approach and the transobturator approach as far as safety and effectiveness.

So, ladies and gentlemen, at the end of the day on the issue of whether this device is safe and, safe and effective or whether it's defective, as, as the plaintiffs contend, I think you're going to conclude that the device is safe and it's not defective.

The other issue that the plaintiffs have brought up is that they've criticized our warnings. Now, it's important to note, and the Judge talked to you earlier, that Boston Scientific's duty to warn goes to the physicians, not to the patients. And there's a reason for that.

This is a product that is lawfully sold that has been through certain procedures and it's sold in the United States. And we sell it to physicians and we have warning material called the DFU that goes to the physicians.

And these physicians don't just rely upon our warning material. They are educated about these products because they use them every day. They go to conferences. They read journals. They read about the risks and the benefits of products.

So, it's not just the manual that they get from Boston Scientific that they rely upon when they treat their patients. They rely upon their whole clinical experience and all of the scientific literature.

And we did tell doctors in this material, and you're going to hear a lot about that later, this product is intended for use only by clinicians with adequate training and experience. The physician is advised to consult the medical literature regarding techniques, complications, hazards, associated with the intended procedures.

And, again, all of the articles that we talked about, including the Ross study and the Cholhan study, they're out in the marketplace for doctors to review. It discussed the potential complications.

And, ladies and gentlemen, these doctors, the three doctors who are the main characters of this case, these doctors did discuss the complications of this procedure with these ladies. And these doctors will tell you that they described all of the relevant risks of the procedures to their patients.

Here are some of the potential complications that are listed in our material. It talks about, "Tissue responses to the implant could include vaginal extrusion, erosion through the urethra or other surrounding tissue, migration of the device from the desired location, fistula formation,

inflammation. The occurrence of these responses may require removal of the entire mesh."

And, ladies and gentlemen, there's no dispute that these doctors knew that mesh when it's placed inside the body, it's meant to be permanent. That's the essence of the use of mesh. It has small holes in it. And when it's placed within the tissue, the tissue grows in between it, in between it and into those holes, and that's what provides the support. And the doctors knew that and they explained that to their patients.

It talks about known risks of surgical procedures for the treatment of incontinence, including pain. You're going to hear that some of these ladies have complaints of pain. Boston Scientific told the surgeons that this will include a risk of pain -- and these doctors already knew that -- and risk of infection, erosion, device migration, complete failure of the procedure resulting in incontinence and mild to moderate incontinence due to incomplete support or over-active bladder.

And here's a list of the other potential complications: Allergic reaction, abscess, detrusor instability, pelvic and vaginal pain, dyspareunia. What's dyspareunia? That's pain with sex.

Some of the ladies here, you've already heard Mr. Love say, have complaints that after they received the

Obtryx, they have pain with sex. It's right here in black and white for the doctors to read and provide that information to their patients. It talks about vaginal bleeding, vaginal discharge, dehiscence, vaginal incision, and on.

And all four of these ladies signed informed consents after they talked with their doctors. We probably have all been through the experience of having a procedure, hopefully not, but if you have or if one of your loved ones have you know that doctors take a lot of time explaining the risks and benefits. And ultimately if you want to ask more questions, you can.

Ultimately, you have to sign a form, informed consent basically saying that you consent to the procedure.

I'm not going to spend a lot of time on this, but the last issue that you're going to have to address after you address whether the product is defective or these warnings are inadequate, you have to address the issue as to whether these women's complaints are actually caused by some type of defect in the product.

And it's important to know what you're looking at, the product, you have to look at whether the product is reasonably designed. Again, you have to weigh the risks and the benefits of the product.

So, even if one of these women did develop a complication from the product, that doesn't mean that the

product is defective. That may mean that this person happened to fall within the small group of people that experience a complication. It goes back to what I talked about right at the start. There is no guarantee with any type of surgery. There's no guarantee with any type of drug.

Ms. Campbell has complaints of pain, erosion. She had a minor revision and she has pain during sex. And, again, I'm only bringing up these issues because that, those are the claims in the case.

But we're going to bring out her prior conditions of pain and pain with sex even before the Obtryx. And you'll see that there's multiple incidents. She has the Obtryx later after 2009, but even before she had multiple incidents of pelvic pain, chronic pelvic pain, dyspareunia, pain with intercourse, severe dyspareunia.

You're going to see medical reports. This one, I know you can't read it. The doctor records actually before she gets the Obtryx that she has pain as a result of sex like she feels like she's being stabbed with a knife.

Here's the reference here and you'll see that. It says, "In her case feels like being stabbed with a knife." This is all before the Obtryx was implanted into her body.

After the implant you're going to hear from Dr. Bhanot. And Dr. Bhanot is going to say that there is a time period when he tells these ladies, he tells all patients, "You

should not do certain things for a certain amount of time."

Dr. Bhanot believes that she engaged in intercourse before the healing period was over and this caused the erosion or one of the major complications that she has.

Ms. Wilson complains. Her complaints are pain, urinary issues, and some emotional and psychological stress. You're going to see information about her urinary issues and that this is Dr. Bhanot's records. When she went to see him he says she has had no problems post-operatively for three years. She has come back to the office only one time in the immediate post-op.

Says down here, "46-year-old female status post-ureterolysis for urethral stenosis following obturator tape and anterior repair. Symptoms have improved. She no longer has suprapubic pain and feels that she empties her bladder much better."

You're going to see that the doctor noted that, "Patient's symptoms have completely improved regarding urination."

You're going to also see that after this incident her complaints of pain are also attributable to some other issues.

And you heard Mr. Love talk about that these ladies do have other issues. Again, that's all part of the aging process that they do have other issues. And part of your job is going to be to figure out, well, is it truly related to the

Obtryx or is it related to some type of pre-existing condition or other condition?

Ms. Blankenship. She has these complaints. And you're going to hear that she has a pre-existing history of chronic pelvic pain, vaginal infections, dyspareunia. She also had depression and anxiety before she had the Obtryx implanted.

I don't want to belabor this point, again because of the time. But, again, you will see extensive evidence showing that she had some of the same complaints she's now making that are related that they believe, plaintiffs believe are related to the Obtryx. She had a lot of these complaints before.

And Ms. Tyree. Her complaints are inability to have sex. She has pelvic and vaginal pain and re-occurrent SUI.

Again, you will hear information about prior chronic pelvic pain and pain with intercourse that existed prior to the implant of the Obtryx. This is brought up solely so you can make a determination as to whether the Obtryx caused these complaints or something else.

And here's information about her post-implant complaints. She had no complaints of pelvic pain until almost three years, greater than three years after the implant of the Obtryx.

So, ladies and gentlemen, I know I've taken up a fair amount of time and I appreciate your patience in listening to

me today. At the end of the day, what you're going to be faced with is the proposition that these ladies, even if they have experienced some type of complication, a known complication, that doesn't mean that the product is defective. This product -- it's going to be undisputed that the mid-urethral sling, and the Obtryx is one of them, is the most common and clinically accepted surgical treatment for stress urinary incontinence in the world. Hundreds of studies support the safety and effectiveness. And there's a high cure rate with low complications.

You're going to see that in the literature and you're going to hear that from the three doctors who treated these ladies. And the device at issue has less complications than alternative stress urinary incontinence surgeries.

So, at the end of the day, Boston Scientific will ask you, based upon the evidence, to return a verdict in our favor.

Thank you for your patience.

THE COURT: Ladies and gentlemen of the jury, I'm going to give you a recess. While you're out, do not discuss this case among yourselves or permit anyone to discuss it with you or in your presence. And please be in your jury lounge at 20 minutes after the hour.

We'll stand in recess for your purposes.

(The jury left the courtroom at 11:05 a.m.)

THE COURT: Counsel, it's been brought to my attention that you have an issue that you want to raise with respect to the videotaped depositions that you intend to offer into evidence here this morning.

MR. MONSOUR: Your Honor, we have -- we would like to play some video depositions today involving Mr. Evan Brasington who is the Vice President of the company and a Mr. Rob Miragliuolo who is a Vice President of the company.

Boston Scientific has objected to these lines of questioning. We were going to -- these have been addressed preliminarily by the -- these have been addressed primarily by Judge Goodwin's rulings. As you are aware, some of these were brought up the other day. And, so, we are bringing these issues in front of you now to discuss the relevance of the ProteGen sling and why such testimony about it would be relevant.

I would first start off, Your Honor, by noting in Mr. Adams' opening he said, "The first sling that we ever sold was the Advantage Lynx sling." And that's not true. The first sling they sold was called the ProteGen sling and they had to recall the ProteGen sling because it had numerous problems.

Why is that relevant here? It's relevant here because they did the same testing on the ProteGen sling as they did on the polypropylene slings.

Let me go back one step. ProteGen was made out of a

different material than the polypropylene slings. It was not made out of polypropylene. It was made out of this collagen infused sort of graft. But it was used for the same treatment.

Now, what they did is they launched the ProteGen. They did not do extensive testing. They did not do clinical testing on the ProteGen.

They then did a clinical study later on, found out that it was problematic, and had to recall the product.

At the conclusion of the ProteGen debacle, they went back and they analyzed the situation and they put together a ProteGen task force of which Mr. Brasington was actually a member. And they went back and they looked at the ProteGen issue and they said, "What should we do in the future?"

Well, one of the documents we want to play with Mr. Brasington talks about how in the future we need to do a better job of risk assessment. And then they also determined in another separate document, they say, "In the future for all future sling materials we will gather clinical data, clinical being data that is derived from actual use inside the human body."

Why is this important? It's important because Boston Scientific looked at its past conduct as to how they bungled a prior sling product. And they said, "In the future we want to do certain things." In other words, they set their own

standard of care.

And then on their immediate next product they didn't follow their own standard of care. They disregarded those rules. They did not gather clinical data. And they proceeded to market, as Mr. Love pointed out. They didn't do any clinical trials first. They did a little biocompatibility and they started selling the product.

And, so, what we argue is on the chart that Mr. Adams showed -- and he goes back and he starts talking about the -- he starts talking about the timeline of the sling, the timeline of polypropylene urethral slings.

But if you look at it -- and I'm a little far away and I apologize. But if you look -- if you go back in time, we need to add in a little more. And that's the ProteGen story because if you look at his chart, you notice that the TVT product comes out. It's around on the same time as the ProteGen is on the market. And then you notice the Boston Scientific Advantage sling is the last retropubic sling that's to be added to the market.

Well, why are they the last polypropylene sling that enters? It's because the company was, in essence, licking its wounds from the ProteGen debacle. So, it's the first chapter of the story that we would like to tell.

And, so, that's the basis as to why we think ProteGen is relevant to these cases because it's the company itself

setting a standard of care for future slings and future sling materials and then not following up with it. And that's the basis of our offer, Your Honor.

THE COURT: Response, counsel.

MR. ADAMS: Yes, Your Honor.

I was very careful to note -- and, in fact, Mr. Monsour talked about my slide and said it applied to slings. I was careful to note that it is a timeline of polypropylene mesh mid-urethral slings. This case is about polypropylene mesh mid-urethral slings.

The ProteGen, as Mr. Monsour has talked about, is an entirely different type of product. It is a polyester product that was coated with bovine collagen and there was problems as a result of that product.

But in no way is it relevant to the issue of the safety and efficacy of polypropylene mid-urethral slings. And I was very careful to walk through that history and not talk about the prior history of the ProteGen or anything prior to the TVT.

The TVT was the first polypropylene sling to come out. And his argument is akin to saying that, "Well, Ford, because you made a sedan in 1980 that is, for example, the Focus, somehow everything you learned about in the Pinto debacle in the '70s should come into evidence."

That doesn't come into evidence because the devices

are not substantially similar. Case law talks about if, if any type of history of defects have to come in, they have to be substantially similar products. These are not.

And then also there is a huge 403 issue. For this jury to hear that we had another product made of entirely different material coated with cow collagen is a total side issue that should not come into this case. It's not relevant. And any relevant value is far outweighed by the prejudice under 403.

THE COURT: All right, counsel.

Rebuttal argument?

MR. MONSOUR: I would -- if you look at the -- first off, we are bringing these cases under a negligence and a strict liability standard. So, under negligence you would want to know what a reasonably prudent manufacturer would do.

And I think Boston Scientific would argue that they are a reasonably prudent manufacturer and that when they set their own standards that those would be reasonably prudent that they then breached.

So, I think it goes straight to the duty question for your consideration as the Court. So, I think it would be appropriate there.

Second, in the note from the ruling by Judge Goodwin, he notes that in the *Ethicon* trial he did not allow the ProteGen story in. But that's a different situation. He

notes that because they were only offering it for the fact that it was their product that had been recalled. Ethicon then used it and they developed the TVT.

This is different. They were not able in that case to use it to set the standards for what the company was violating because it was Ethicon versus Boston Scientific. This is Boston Scientific itself. And this is a subsequent Boston Scientific product.

So, you have a completely different scenario than when the Judge did not allow it in the *Ethicon* case. That's why he's asking us to bring you this evidence so I can relate why it would be relevant. It's very relevant in this case because -- and I can show you this. There's a key points document. And if you would like me to approach, I can hand it to you.

THE COURT: Sure.

MR. MONSOUR: This document, Your Honor -- where would you like me to come? Right here?

This document is the first document, Your Honor. We call this the key points document. And this document has been used in numerous depositions. And it's a summary of what I mentioned before.

It says, "In connection --" it's the part I've highlighted. "In connection with any future sling materials Boston Scientific will gather clinical data to assess product

performance in a broad spectrum of clinical situations."

If you turn over the page, there is a whole question and answer session which talks about what the company did before it put the product on the market.

And if you look, if you look, you can see that on the second page, Your Honor, it talks about, "On what basis did you make the decision to launch the product and keep it on the market?"

And then it mentions that prior to its release and answer, the product met all of the standard engineering and biocompatibility testing commonly applied to implants and satisfied all U.S. and European regulatory requirements.

Well, why is that important? Because that's what they did here. They realized that in this situation by doing the minimum amount of biocompatibility testing you can get a product onto the market, but it's still not safe.

And, so, they make the conclusion, which is highlighted for you on Page 1, "In the future we don't need to do that anymore." And that is why this is so important. This topic of ProteGen is so important. It's how should this company act?

And to show you how specific it is, Your Honor, the ProteGen -- this is not for a different type of product. This is for a sling used to treat stress urinary incontinence.

And what they say, you can look at this document

because you can determine from this document that they might be looking at future sling materials because they say for future sling materials this bovine collagen obviously was a complete disaster. And that's why they say for future sling materials.

They were contemplating at this point in time doing the Advantage sling, getting into the polypropylene market because they're watching the folks at Johnson & Johnson make a killing off of the TVT.

And, so, they say, "With future sling materials we're going to test it. We're going to gather clinical data first." And that's why this is so important. They set it out for these very products and then they don't follow through. And that's why we think it should come in, Your Honor.

THE COURT: All right. What is it, Mr. Adams?

MR. ADAMS: I just wanted to address one point. May I do that, Your Honor?

THE COURT: Go ahead.

MR. ADAMS: There is no evidence that at the time these statements were made that Boston Scientific was getting into the sling market. There's going to be no testimony on that issue at all.

The other thing that is really important to note that, again, goes to the 403 analysis is Mr. Monsour referenced this, Page 2. It says, "This product was cleared

by the FDA and properly launched in the marketplace."

Again, this highlights the prejudice for this type of information involving a product that they admit is not substantially similar. A substantially similar product would be a polypropylene product that this case is all about.

So, we're talking about a product made out of different material, including this bovine collagen. For it then to come into evidence and us not be allowed to state the fact that the FDA does not require testing would be extremely prejudicial.

It, it highlights the prejudice because with the ProteGen no testing was required. Boston Scientific before the Obtryx came out with the Advantage relied upon existing studies and testing. There is simply no reason why this Court should allow information like this on the ProteGen to come in.

Again, the best example I can give you is information about Ford's debacle with the Pinto somehow coming in in a later case. And there's actually cases on that that talk about under a 403 analysis that type of information shouldn't be allowed even on the issue of punitive damages or product defect or negligence.

Thank you for your time, Your Honor.

THE COURT: All right, counsel. With respect to this issue, the Court addressed a motion *in limine* with respect to the ProteGen device. You all have referenced it --

Or at least, Mr. Monsour, you've referenced it in your arguments.

The Court wanted to see the context in which it was sought to be introduced before making a final decision about its admissibility.

There has been some opening statements and, of course, there will be evidence here regarding the statement that Mr. Love brought out that was given to Boston Scientific regarding clinical testing.

This statement with respect to a different device -- and I think to some extent it's being argued much more narrow than it is, that in connection with any future sling materials Boston Scientific will gather clinical data to assess product performance in a broad spectrum of clinical situations.

I find that this is, in fact, relevant information. I further find that it is admissible given the statement that's going to be offered. It goes to the knowledge of the defendant. It also is evidence that would go to punitive damages if punitive damages are ultimately proven. This is an issue that can go to punitive damages given the elements that the plaintiff is required to prove in order to get punitive damages to the jury.

And I find, given the nature of this case, given that warnings and the fact that a defective device was given to these plaintiffs through their physicians that this is

admissible.

I further find that in light of that that its probative value is not substantially outweighed by any undue prejudice.

And, so, I am going to allow the evidence, preserving the defendant's objection and exception. And I am willing, counsel, to give an instruction regarding its limited purpose if requested to do so.

MR. ADAMS: We would, Your Honor, and we'll prepare that. I might make one request.

THE COURT: Yes, sir.

MR. ADAMS: This document is Exhibit 53 on key points. The -- I would suggest that the Court only allow in the first page and not the information about the recall of the ProteGen.

Again the Q and A that follows, there are multiple references to the FDA and the clearance process for -- the fact that we are not allowed to bring up the fact that the Obtryx was cleared by the FDA, for then this document to come in as is I think again would be extremely prejudicial and confusing.

And I think, frankly, it should open the door -- if this came in, it should open the door to the fact that the Obtryx was cleared, which I know Judge Goodwin has already ruled upon.

So, again, for the purpose that the Court is allowing this document to come in, I think the first page suffices to reduce the prejudice.

THE COURT: The Court has previously ruled with respect to any FDA regulations. And, of course, I'm going to follow that and keep it --

Mr. Monsour.

MR. MONSOUR: We will redact out the FDA portions, Your Honor. We anticipated this. We will not cross the FDA line and violate Judge Goodwin's rulings I promise you.

THE COURT: All right. I want to see what your redactions are and I'll give you a final ruling on the document. Let's take a break until about 11:30 and come back.

(A Recess was taken from 11:23 a.m. to 11:34 a.m.)

THE COURT: Plaintiff, call your first witness, please.

MR. LOVE: Your Honor, at this time plaintiffs would call Evan Brasington, Boston Scientific's vice-president of worldwide marketing.

THE COURT:

MR. LOVE: And the video cut is 32 minutes.

THE COURT: All right. Ladies and gentlemen, you will recall that those witnesses who appear by video, you are to assess their credibility the same as you would and to view their evidence the same as you would if the person appeared

here in person before you.

(The video testimony of EVAN BRASINGTON was played from 11:35 a.m. to 12:07 p.m.)

MR. LOVE: That concludes plaintiffs' proffer, Your Honor, for Evan Brasington.

THE COURT: All right. Mr. Strongman?

MR. STRONGMAN: Boston Scientific has about a 19-minute offer for Mr. Brasington.

THE COURT: All right. Thank you.

(The video testimony of EVAN BRASINGTON continued at 12:08 p.m. to 12:28 p.m.)

MR. STRONGMAN: That concludes Boston Scientific's offer on Mr. Brasington.

THE COURT: All right. Thank you, Mr. Strongman.

Ladies and gentlemen, I'm going to give you your luncheon recess. While you are out, do not discuss this case among yourselves or permit yourself -- or permit anyone else to discuss it with you or in your presence.

Please be in your jury lounge at 1:30. We will stand in recess.

COURT SERVICES OFFICER: All rise. This Court is in recess.

(The Jury left the courtroom at 12:28 p.m.)

(A luncheon recess was taken at 12:29 p.m.)

(The Jury entered the courtroom at 1:30 p.m.)

THE COURT: Good afternoon, everyone.

Counsel, call your next witness, please.

MR. LOVE: Your Honor, at this time we would call Boston Scientific employee Charles Smith who was the Director of Development/Sustaining Research, and that video clip is 11 minutes and 41 seconds.

THE COURT: All right.

MR. LOVE: Looks like we are having a technical difficulty, Your Honor, with some audio. If you give us just two seconds, I think we can clean it up.

THE COURT: Yes, sir.

MR. LOVE: With the Court's permission, we can certainly call Peggy Pence now live and then fix this maybe at a break and then play videos this afternoon.

THE COURT: All right.

(Audio began.)

MR. LOVE: (Indicating.)

(The video testimony of CHARLES SMITH, JR., was played at 1:35 p.m.)

MR. LOVE: That concludes the plaintiffs' portion of the depo.

THE COURT: Mr. Strongman?

MR. STRONGMAN: Nothing further from Boston Scientific at this time.

THE COURT: All right. Thank you. Call your next

witness, please.

MR. LOVE: The plaintiffs would call Dr. Peggy Pence.

THE COURT: Dr. Pence, will you come up and take an oath or affirmation, please?

THE WITNESS: Yes, ma'am.

THE DEPUTY CLERK: Would you please raise your right hand.

(**PEGGY PENCE**, **Ph.D.**, HAVING BEEN DULY SWORN, TESTIFIED AS FOLLOWS:)

THE WITNESS: Yes, I swear.

THE DEPUTY CLERK: Please take stand.

THE WITNESS: Thank you.

THE COURT: Counsel, let me see you here, please, at the bench.

MR. LOVE: Sure. Your Honor, may I bring Dr. Pence a glass of water?

THE COURT: Yes, sir.

(The following occurred at sidebar.)

THE COURT: I don't know if there are documents that you plan to use that have not been admitted, but I don't want the jury shown anything that's not being admitted unless there is an agreement between the two of you that there is no objection to its admission. The clerk has control of these other screens, of course, not for the large screen, so I want you all to be careful about what goes to the jury.

MR. LOVE: How would you like me to handle that? Say Exhibit Number 233, do you have any objection -- I would like to offer 233 and I have got copies for both of you. I apologize. I didn't bring it.

THE COURT: I want them to be admitted before they are shown to the jury.

MR. LOVE: Okay.

THE COURT: So that's fine, if there is an agreement that there is no objection.

MR. ADAMS: I don't know what he's going to --

MR. LOVE: I will give both of you a notebook as soon as I head back there. With respect to studies, do I just ask, may I publish Exhibit 234 which is a study?

THE COURT: I want to know if there is an objection before anything is shown to the jury.

MR. LOVE: Absolutely.

MR. ADAMS: I wanted to add, too, this, as you're aware, Judge, this expert, this is a professional expert, there was a *Daubert* ruling by Judge Goodwin. He basically allowed her to testify about one opinion: Should premarket clinical testing have been done? Now I'm getting an inference that she may be looking at studies done that was after we launched it. I don't think -- again --

THE COURT: He has precluded any postmarket studies, and he's also precluded any opinions with respect to

marketing. Those are the two -- or labeling, I'm sorry. Those are the two opinions that he has excluded with respect to Dr. Pence.

MR. ADAMS: Yeah. The only opinion she can give is whether we should have done premarket clinical studies. So what I'm alerting the Court to, I don't know what counsel plans to do, but I would think that that is a pretty limited area that she can testify to.

MR. LOVE: Just so the record is clear, if you look at his order specifically, he specifies pages within the report that he found acceptable for the testing opinion that she's going to offer. Some of those studies postdate marketing but predate any -- they were not marketed to my client specifically. My client's surgeries are in 2009, '10 and '11. And so the marketing, the premarketing testing opinions, I don't think are limited.

In fact, he specifically cites pages that he authorizes her to testify on, where studies do postdate the marketing of this particular product. What he specifically allowed her to do was talk about the test date, whether it was appropriate based upon what was feasible at the time. And what's important with respect to what they could have done prior to marketing is that they actually performed studies that could have been done premarketing, had they done -- the scientific technology was available to do the exact things

she's going to say should have been done.

THE COURT: I don't know, but the jury is here. Both of you have the judge's opinion, and I'm going to expect you to live within the confines of it. If you hear something, Mr. Adams, that you have objection to that the Court has excluded, I will deal with it. It may be that you don't hear anything. I expect you both to live within the confines of the judge's ruling.

MR. LOVE: Absolutely.

MR. ADAMS: And, Your Honor, I wanted to give you an example. If she starts going into studies, like the Ross study or the Cholhan study, I think that's clearly beyond premarket. She can say those -- a type of randomized clinical trial should have been done, but she can't talk about our studies, and I don't know if you're going to go there.

MR. LOVE: I think she can. I think she can say the Ross study is a randomized controlled trial, and it was done in 2009, and talk about fact that it was scientifically feasible for this company to perform that very study prior to marketing. Her whole opinion is they should have done a randomized controlled trial but they were not capable of doing it.

MR. ADAMS: She doesn't need to reference Ross or any of the other studies. She can talk about -- again, he allowed her opinion on the limited issue of what -- Boston Scientific

should have done premarket clinical testing. She can say that should have been a randomized clinical controlled trial, but there is no need -- and Judge Goodwin is not allowing her to testify about actual studies.

MR. LOVE: She has been -- go ahead. I'm sorry.

THE COURT: He sets forth, gentlemen -- maybe you all need to go back and read it, but he sets forth the opinion on 58 of his ruling. He then goes into the argument that's been made by both of you. He ultimately agrees with the plaintiff that this opinion does not have the same problems it did in the previous case where he excluded it. He indicates that that opinion -- the motion is denied, he grants the opinion -- or the motion as to postmarketing and as to the labeling. That's what I see here. And so I think that she's permitted to give this opinion, Mr. Love.

MR. LOVE: All right.

THE COURT: And I preserve an objection and exception to you if you have some quarrel with the Court's interpretation of that ruling.

MR. LOVE: Thank you.

MR. ADAMS: Okay.

(Sidebar concluded.)

MR. LOVE: Your Honor, would the Court like a copy so you can follow along as well? These are going to be exhibits that may be discussed during her testimony.

THE COURT: All right. Thank you.

MR. LOVE: May I approach?

THE COURT: Yes. Thank you.

MR. LOVE: Thank you.

Your Honor, one last final request, is it possible that we can get that screen turned on? I think you have to do it from where you're at or someone.

THE COURT: Counsel, in our discussion here, I want to also make sure you all understand that I of course, did not intend to exclude the basis of this opinion.

MR. LOVE: Oh, I apologize. I couldn't --

THE COURT: It was not my intention during our discussion here at the bench to exclude the basis of this opinion.

MR. LOVE: Sure, thank you, Your Honor.

THE COURT: All right.

MR. LOVE: Your Honor, may I proceed?

THE COURT: Yes, sir.

(DIRECT EXAMINATION OF PEGGY PENCE, Ph.D. BY MR. LOVE:)

Q. Good afternoon, Dr. Pence.

A. Good afternoon, Mr. Love.

Q. How are you doing?

A. I'm doing fine. Thank you. How are you?

Q. I'm fine, thanks. We've got a tough job this afternoon. We've got to kind of keep this jury entertained after lunch

when everybody kind of gets tired.

Would you please introduce yourself to the jury?

A. Good afternoon. My name is Peggy Pence. Nice to meet you all.

Q. Okay. Are you a doctor, a Ph.D. doctor?

A. Yes, I am.

Q. Do you mind if I call you doctor?

A. No, that would be fine, thank you.

Q. Dr. Pence, tell the jury what you do for a living.

A. I am a consultant to the medical device and pharmaceutical industry, and I help them to develop the strategy for marketing their products when they have a new product idea, and help them to determine the types of testing that they will need to do, both what we call preclinical and also clinical testing prior to marketing, that will enable them to be able to market their product.

Q. Okay. Let's talk a little bit about your education. You do have an undergraduate degree?

A. I do.

Q. All righty. And what is your undergraduate degree in?

A. It's in microbiology.

Q. Okay. Where did you get that degree?

A. Louisiana Tech.

Q. Perfect, perfect. Okay. And do you have any graduate degrees?

A. I do.
Q. All right. You said microbiology, your undergraduate degree?
A. That's correct.
Q. What is microbiology?
A. It's the study of microorganisms, bacteria, viruses.
Q. And you do have, you said, a graduate degree?
A. I do.
Q. And in what?
A. My major is pharm -- is toxicology and my minor, pharmacology.
Q. And real briefly, you have a Ph.D. in toxicology, I understand?
A. That's correct.
Q. What is toxicology?
A. Toxicology is basically the study of poisons, and as it's applied to the medical device industry and the pharmaceutical industry, it's looking at the adverse effects, the potential toxicity of medical devices, the materials that medical devices are made of, or the adverse effects from drugs.
Q. Okay. Let's talk a little bit about your experience. Have you ever worked for a pharmaceutical or medical device company?
A. Yes.
Q. All right. Let's take a look at this slide here. Let me

get this thing to work. There you go.

I have on this slide, I pulled some information off of your C.V., and I just wanted to summarize it for the jury's benefit. Are these some of the companies that you've worked for over the past 30 years?

A. Over the past 40 years.

Q. Over the past 40 years, I'm sorry.

A. Over 40 years actually.

Q. I was trying to protect your age.

A. Thank you. I appreciate that.

Q. So it looks like from 1970 to approximately 1992, you worked at a number of different pharmaceutical and/or medical device companies?

A. That's correct.

Q. If you could, just explain to the jury what types of jobs you held at each of these types of companies.

A. I held a variety of jobs. When I first started out at Eli Lilly and Company, I was working in the basic research laboratory, developing methodologies for testing potential new drugs to see if they might have a purpose or -- for treating immunological diseases, and from there I moved into clinical testing.

And from there, I moved to Serono Laboratories where I had responsibility for managing clinical trials, for designing and managing clinical trials, and at Triton Biosciences, I

held a project management position, and what I did there was to oversee all aspects of product development.

At that point I had realized that I wanted to have my own business someday, and so I wanted to understand the full process of product development better. So as a project manager, I worked with people in manufacturing, through preclinical testing, clinical testing, all the way through, working with people that would be watching a product, should we be able to prove safety and effectiveness for marketing. And then at Amgen, I was responsible for clinical trials.

Q. Perfect, perfect. Now, you said a number of things that I would be interested in and I think the jury might be interested in as well, but I want to take this one step further.

You said you started at your own company. What's the name of your company?

A. Symbion Research International.

Q. Okay. And Symbion Research International is identified here. Explain to the jury the types of work that your company does.

A. As I mentioned, we're a consulting and contract research organization. We work with different companies, medical device, pharmaceutical companies, who identify a product that -- that they would like to take to the market, and help them to do various aspects of product development, in

particular, helping them to determine what types of testing they'll need, both preclinically and clinically, and then helping them to design the studies and overseeing the conduct of those studies, amongst other types of activities.

Q. Perfect, perfect. Okay. And it looks like you do consulting work currently for pharmaceutical companies, is that fair?

A. That's correct.

Q. Biopharmaceutical companies, is that fair?

A. That's correct.

Q. As well as medical device companies?

A. That's correct.

Q. And you do that in all areas of product development?

A. That's correct.

Q. Okay. We're going to talk about product development in just a minute, but the last thing here is litigation support. When did you start doing this type of work?

A. About five to six years ago.

Q. Okay. Why did you get interested in this type of work?

A. I was first contacted to -- to work with attorneys that were involved in some product liability cases, and about five -- about six years ago, actually, and decided that this is an extension of my teaching. I -- over the years, I've been in this industry for over 40 years, and I think it's important to share the knowledge and experience and hopefully

wisdom that I've gained over those periods of years through teaching.

So I teach students and from -- with different backgrounds at this point in time, and I see this as really as an extension of teaching, sharing the knowledge and hopefully, again, the wisdom that I've gained over the years to let others understand about product development, the types of testing that goes into products that are marketed for medical conditions.

Q. Okay. Fair enough, fair enough. Let's talk about product development. That's kind of why you're here today, right?

A. Yes.

Q. Okay. Product development, what does that encompass and walk through it. I know this slide isn't the best slide because I think if we were being accurate, all of these little bullet points would be within the bailiwick of product development, fair?

A. That's correct.

Q. Okay. If we could, walk the jury through what product development entails and why it's important when you're putting new medical devices on the market.

A. Well, product development encompasses all aspects of design and testing that need to be accomplished in order to get a product on the market. So from the manufacturing

process and in the case of a medical device, from designing it, understanding what user needs are, what is the product going to be used for? And then designing the product to meet that need.

And once you've designed the product, you have to test it to find out -- to determine does it meet the needs for which you're developing it? Can it be used in -- for the intended use, again, for what you're developing it?

And then the preclinical testing and the clinical testing are -- you do the preclinical testing first before you go into the clinical testing, again, are confirming that the product is safe and effective for the use for which you intend it.

Q. Okay. Let's talk about two other quick points. Preclinical and clinical testing. The jury has heard these terms in opening statements and may have heard it through one of the witnesses they've seen already. What is preclinical testing? How is that defined?

A. Preclinical testing is the testing that is done prior to testing in humans. And sometimes we also continue preclinical testing after one starts into human clinical trials, depending on what the project may be. But there are certain tests that you must do before you put a product into humans because you have to justify that the product is safe enough and has a potential benefit for humans before you subject humans to the

potential risks of giving -- using a new product on them. And preclinical includes laboratory testing, that can be in a test tube type situation, or in animals.

Q. Okay. Let's talk about clinical trials and explain just briefly what a clinical trial is.

A. Clinical trial is testing in humans.

Q. Okay. And I've heard the term randomized controlled trial. What is that?

A. A randomized controlled trial is what we call the gold standard or best evidence kind of a study that's done because subjects, humans, are randomly allocated to a treatment. In a randomized controlled trial, the purpose of that trial is to compare two or more different treatments. And because you're randomly assigning patients to treatment, the purpose of that is to reduce bias in the trial.

Q. And in reducing bias, that's why it's kind of considered the best type of evidence to establish safety and efficacy?

A. That's correct, the data is most reliable.

Q. Okay. We're going to focus most of our time here today talking about premarket testing that could or should have been done, but I want to finish up with your background real quick, if we could.

Do you serve on any boards or hold any memberships in organizations that are relevant to your opinions in this case?

A. Yes, I have in the past and do currently.

Q. Okay. Tell the jury about a few of those so they can kind of get a feel for who you are.

A. I participated in the Clinical Trial Program Certificate Advisory Board through California State University at the Fullerton campus to develop a certification program in clinical trials for people with appropriate backgrounds who might be interested in working in clinical development. So hopefully by completing a certification program, that would not only give them the background information they need, but enable them to get a job in the industry, in doing clinical trials.

I also have served on the Biotechnology and Healthcare Advisory Board in California State University on the Channel Islands campus. And I served on a nonprofit board as well for the, what used to be the CareNow Foundation is now called the CompassioNow Foundation.

Q. And what is the CompassioNow Foundation briefly?

A. CompassioNow is, again, as I mentioned, a nonprofit, and our mission is to provide medical care to the world's least served. We've been principally working in various countries in Africa, Uganda, Tanzania, Zambia, and funding local clinics and also a Mission Medic Air, a flying clinic, if you will, for outreach to communities that are very rural, and providing us medical supplies, both medicines and equipment, and funding for doctors and nurses for those clinics.

Q. Okay. Last topic on your experience, teaching experience, do you have any?
A. Yes, I do.
Q. Okay. Tell the jury a little bit about your teaching experience as it pertains to the issues involved in this case.
A. In -- I mentioned the Clinical Trials Certificate Program Advisory Board on which I served. I also went on to develop one of the courses for that certificate program on clinical trials project management, and taught that at California State University, Fullerton campus, and I have now for several years been part-time faculty at the California State University, Channel Islands campus, teaching graduate students in biotechnology a course on clinical trials and quality assurance.
Q. Okay. And who are your students over the years, who have you taught?
A. I've taught both industry professionals and graduate students in the healthcare field.
Q. So you've actually taught industry professionals or employees of medical device companies about the very issues you're going to talk about today?
A. Yes. In addition to the -- the university teaching that I've done, I've also done a number of different workshops at companies and chaired conferences and given speeches in the area, some of the areas that we're talking about today.

Q. Okay. Perfect. Well, let's get into the work you've done in case. What did I ask you to do in this case, Dr. Pence?
A. You asked me to perform an investigation to determine whether or not Boston Scientific Corporation had done the appropriate testing of its Obtryx sling for marketing of the product.
Q. Okay. And we'll get to that opinion in just a minute, but what types of materials did you need to review in order to complete your investigation?
A. I reviewed a large variety of materials, including many corporate documents, various types of reports, e-mails, internal correspondence, numbers of different types of documents, as well as a number of different depositions of employees and other people involved in -- with Boston Scientific in the development of its sling products as --
Q. Let me stop you right there, okay, because you mentioned a few things, and I want to just break this down a little bit. You had to review internal documents?
A. That's correct.
Q. Internal documents, you mean documents that Boston Scientific has produced in this litigation?
A. That's correct.
Q. Okay. And then you said depositions?
A. That's correct.

Q. Are you talking about depositions of Boston Scientific employees?
A. That's correct.
Q. Okay.
A. And other related --
Q. We're going to get there.
A. Okay.
Q. What about -- what is it about the depositions and the internal documents that were important in your investigation?
A. In order to do an appropriate investigation, I have to go back in time and get an insider's look. I need to know the what, when and why. I need to know what was known, when it was known, and what decisions were taken by key personnel and why those decisions were taken.
Q. Okay. Fair enough. Fair enough. Scientific literature, was it necessary for you to evaluate the available scientific literature?
A. Yes, definitely.
Q. And why is that important in your investigation?
A. The scientific literature is important for a couple of reasons. The first is I needed to see if there's any information or any publications available in the scientific literature about the Obtryx sling. Have any tests been done and published on the Obtryx sling? I needed to know that information.

Secondly, I need to know, for different products that might have -- that would be used for the same purpose or similar type of mesh but different, for example, I also needed to know what information is known about those, what kinds of problems, issues there may have been, whether or not they were effective as well.

Q. Okay. So we've got scientific literature, we've got depositions, we've got internal documents. Was there any other information that was necessary for you to complete your investigation in this case?

A. I did some of my own independent research, definitely.

Q. Okay. Perfect, perfect. Now, have you completed your investigation?

A. Yes, I have.

Q. All right. Have you formed opinions in this case?

A. Yes, I have.

Q. And what is your opinion with respect to what I've asked you to do?

A. My opinion is that Boston Scientific failed in its responsibilities as the manufacturer of the Obtryx sling to perform the appropriate testing for marketing of the Obtryx sling.

Q. Okay. All right. Well, let's explore that opinion, if we can.

Let's talk about the testing that's available and the

testing that you deem is appropriate in this case.

In your experience, what types of tests or studies are necessary to ensure that a product is safe before it is made available for sale for a permanent implantation?

A. There are a variety of different types of studies that are -- that are required, that are necessary.

Q. In this case, with respect to the Obtryx sling, what's your opinion with respect to what types of testing should have been done?

A. In addition to bench testing and biocompatibility testing, there should have been additional testing in animals, as I was explaining, and then human testing.

Q. Okay. And is it your -- is your opinion that there should have been randomized controlled trials in humans before it was made available for sale?

A. Yes. Definitely.

Q. And, just briefly -- actually, let's just back up and go through the testing and we'll get to the why in a minute.

A. Okay.

Q. So we talked about the different types of testing and let's just go ahead and -- you're familiar with the different types of testing described here?

A. Yes.

Q. All right. And the jury has heard, I think, all of these so far, but I just want to touch on each of them so they can

get an idea of kind of the purpose behind each type of testing, if we could.

Let's talk about bench testing. What does this tell us?

A. Bench testing basically tells us whether or not the medical device is going to function properly. I mentioned when you design a product, you establish specifications that it needs to meet to meet user needs, and the bench testing talks -- tests to determine whether or not it will meet those user needs, things like, is it strong enough, is it too stiff, does it tear when it's under too much tension.

Q. Okay. Perfect, perfect. Now, this bench testing that's done, is it done in humans?

A. No.

Q. It's done in a laboratory?

A. That's correct.

Q. Okay. Let's talk about biocompatibility testing. Just briefly explain what the -- what the purpose of biocompatibility testing is.

A. Biocompatibility testing is done to determine or predict, if you will, how the medical device, how the materials in the medical device may interact with the human body. And it, however, doesn't determine biocompatibility because it's not done in humans. So, but it is an important step to the next steps, over the next phases of testing, further animal testing

and then human testing, as a mentioned.
Q. Real quick, let's back up. You said, I believe, biocompatibility testing can establish how a device may interact with the human body?
A. Yes, that's correct. It gives some information about how it may interact.
Q. Can it establish how it will interact with the human?
A. No, it cannot.
Q. How do you establish how a product will interact in a human body?
A. By testing it in humans.
Q. Perfect, perfect. Animal studies, let me ask you this: Did Boston Scientific perform any bench testing on the Obtryx sling?
A. Yes.
Q. Okay. What types of bench testing did it perform?
A. They did tensile strength, burst strength, the pore size of the mesh, various tests of that nature.
Q. Okay. Biocompatibility testing, did they perform any on the Obtryx sling?
A. Not on the Obtryx sling specifically. For the biocompatibility, they relied on biocompatibility testing that was done on a polypropylene mesh over ten years before the marketing of the Obtryx sling.
Q. Was that, like, in 1992 or so, is that --

A. 1992, 1993, that's correct.
Q. Perfect, perfect. Now, in the absence of human testing, can bench testing or biocompatibility testing ever establish that a product is safe for permanent implantation in humans?
A. No, it cannot.
Q. Okay. Let's talk about animal testing, but let's go back to testing. In the United States, who's responsible for ensuring that testing is done to establish that a product is safe?
A. That is the manufacturer of the product.
Q. Okay.
A. Boston Scientific --
Q. Okay.
A. -- in this case.
Q. Okay, okay. Now, is this a shared responsibility with anyone?
A. No, it is not.
Q. It's their responsibility, correct?
A. That is correct.
Q. All right. Is it okay for a company like Boston Scientific to rely upon the testing done on other products made by other companies?
A. No. That other testing is important, as I mentioned, reviewing the literature. It's important to what you can be aware of to know that information so that it informs the type

of testing, you get that knowledge, and you apply it to the development of your product. So it's important to know that and factor it into your own testing and development, but it can't tell you how your product will perform.

Q. Okay. Last two, real quick. Animal testing, what's the purpose of animal testing? What is that supposed to give us insight on?

A. Animal testing is the next step in order to, again, determine that the product has a reasonable likelihood of working in humans, and, more importantly, that it -- it is safe enough to be able to take it into human testing. You don't want to expose humans to undue risk.

So it's a gradation, it's a stepwise process of testing, so that by the time you get to humans, you hope that you have established that the product will not cause any undue harm. It doesn't always work that way, sometimes we do see harm in humans, with testing, but the whole -- in clinical trials. But the purpose is to do all we can to determine that it's safe enough for testing in humans before we put it into humans.

Q. Perfect, perfect. Thanks for your time on these issues.

Okay. We are done with the testing now. Let's go on to the Obtryx sling itself.

The jury has heard from Evan Brasington about the ProteGen sling story. Why is that story important to your

opinions in this case?
A. It's important because that was a sling that preceded the development of the Obtryx sling, and I'm not sure what you heard, but that product had some safety issues that caused the company to cease marketing of that product. So they were aware that -- and that product had not gone through clinical testing. So they were on notice, if you will, they understood that by not doing clinical testing before marketing a product, that serious safety issues can arise.
Q. Well, let me ask you this: Have you reviewed as part of your investigation any evidence to it where Boston Scientific assessed whether it was appropriate to do or not do clinical testing prior to the launch of their next product?
A. Yes, I have.
MR. LOVE: At this time, Your Honor I would like to offer Exhibit 759 which is, I believe, the second tab in your notebook and the second tab in yours, Mr. Adams.
THE COURT: Objection, Mr. Adams?
MR. LOVE: It would just be the first page.
MR. ADAMS: Just the -- just Page 261?
MR. LOVE: That's correct.
MR. ADAMS: Your Honor, I'd note my earlier objection.
THE COURT: All right. And it's under which tab, counsel?

MR. LOVE: It's under Tab 759, Your Honor.

THE COURT: All right. I will order that this document be admitted, preserving the defendant's objection and exception, based on my earlier reasoning, counsel.

MR. LOVE: Thank you, Your Honor.

(PLAINTIFF EXHIBIT P-759 WAS RECEIVED IN EVIDENCE.)

(The document was published to the jury.)

MR. LOVE: I pulled it up. Let me see if I can go ahead and do that.

BY MR. LOVE:

Q. Okay. This is a document you have reviewed as part of your investigation, is that correct, Dr. Pence?

A. Yes, it is.

Q. Okay. And what is this document, for the jury's benefit?

A. This is a key learning point document based on the company's experience with the ProteGen sling.

Q. Okay. Let me just go ahead and read it because it's not the best quality copy. It says, "Boston Scientific/Microvasive decided to voluntarily discontinue marketing the ProteGen sling because we could not assure ourselves that it was producing outcomes consistent with Microvasive's standard of performance for its products and because of the variability of outcomes among different centers." Did I read that correctly?

A. Yes, you did.

Q. And the last point is, "In connection with any future sling materials, Boston Scientific will gather clinical data to assess product performance in a broad spectrum of clinical situations."

Now, why are these findings and these conclusions important to your opinions as it pertains to the Obtryx sling?

A. Well, once again, it shows that the company understood that they did not do appropriate clinical testing for the ProteGen sling and, as a result, encountered problems. There were safety issues, people were being harmed. And so the product was taken off the market.

So with that knowledge, that was knowledge they had, that clinical testing is needed to determine safety before they tested the Obtryx sling and marketed it. I mean, before they marketed the Obtryx sling.

Q. What was the date of this investigation, just for the jury's benefit, can you see it up there?

A. Yes. 1999.

Q. Okay. So that was roughly five years before the Obtryx sling was made available?

A. That's correct.

Q. Okay. Perfect. Let's talk about the Obtryx, if we can.

Obtryx, I think it was August, 2004, is that when it was made available for sale?

A. That's correct.

Q. Okay. Perfect, perfect.

The Obtryx sling, how was it different, if it was, from previous sling product made by other companies?

A. Made by other companies?

Q. Yeah.

A. The -- has the jury seen an Obtryx sling?

Q. Oh, they have. In fact, let me get that. Would this help demonstrate your testimony if you were able to have this?

A. Yes.

MR. LOVE: May I approach the witness, Your Honor?

THE COURT: Yes, sir.

BY MR. LOVE:

Q. Just use it at your convenience.

A. Thank you.

So assuming you've seen this earlier, earlier today, this is the polypropylene mesh sling. It's about 17 to 18 inches long. And this center section that sits under the urethra -- and forgive me if I'm repeating things you've already heard, but since I'm not sure what you may have heard -- the sling sits under the urethra. The urethra is the tube through which you urinate. And the center section of this is what they call detang. There is about a little over one-half inch piece of the center of it that is detanged.

If you were able to feel the edges of this, the center section feels differently because they've heat sealed those

edges. And the idea for that piece that sits under the urethra is that with the heat sealing of those edges, that it would resist being distorted when tension is applied during surgery to appropriately tension it so it has the right amount of tension to stop -- to stop the stress urinary incontinence. And, also, that it would be -- the hope was that it would be less irritative to the urethra and hopefully decrease the likelihood of erosion of the sling into the urethra.

Q. Perfect, perfect. Okay.

So the design change made by Boston Scientific was this detanging or heat sealing?

A. That's correct.

MR. ADAMS: Objection, Your Honor. May we approach?

THE COURT: Yes, sir.

(The following occurred at sidebar.)

MR. ADAMS: I object to the testimony. It's outside the scope of the opinion allowed, and here's the problem: This device was cleared by the FDA in the 510(k) process. The FDA found that it is substantially equivalent to other devices. Now they've created the inference that it's not substantially equivalent. That is directly contrary to the FDA finding.

So by them trying to say that the Obtryx is some type of outlier by virtue of these heat-sealed edges, I believe that -- I think we have two options, she can -- Mr. Love can

stop pursuing this line of testimony, or I'm entitled to bring in the fact that the FDA found that the Obtryx sling is the substantial equivalent of other products on the market. Otherwise, this is extremely prejudicial and unfair.

THE COURT: Mr. Love.

MR. LOVE: This is the foundation information of her opinion that they should have done testing. They made changes to this product that were unique. Clearance has nothing to do with safety, and he knows this as well as I do. That's why Judge Goodwin always keeps it out. The fact that a product is cleared does not equal safety. But the problem is this product was different than others that came before it but was similar to it, but substantial equivalence doesn't equal safety.

Her opinion is that these changes -- in part, is these changes should have been tested before they were available for sale to humans, perfectly in line with her opinion that they should have done human testing.

THE COURT: Anything further?

MR. ADAMS: Yes. The whole purpose of the 510(k) process is, if the device is substantially equivalent to another device on the marketplace, as determined by the FDA, then the product is cleared. That -- it's undisputed that finding was made. So for the expert and Mr. Love to now come in and say this wasn't equivalent to the other devices is

extremely prejudicial. If -- I have to be allowed to bring up the fact that the FDA found it equivalent. If they didn't, they would have ordered tested.

THE COURT: Wait until he's done and go ahead.

MR. LOVE: Sure, my apologies.

It's factual they made a design change. Clearance doesn't mean safe. That's why -- that's why Goodwin keeps it out.

THE COURT: Judge Goodwin, he means.

MR. LOVE: I'm sorry. Judge Goodwin. 510(k) has nothing to do with this. It's factual that they made a design change. Nobody is going to dispute that. Her opinion is that design change should have been tested and it wasn't.

THE COURT: Okay. Based on my understanding of where she's going, Mr. Adams, I'm going to overrule your objection. I preserve the objection and the exception to testimony, and the judge has, in fact, made the distinction with respect to safety, and he's keeping out the FDA approval. And so, again, if there's other things you hear you want to make objections, but, based on her testimony, I will overrule the objection, preserving the defendant's objection, the exception.

MR. ADAMS: Understood.

(Sidebar concluded.)

BY MR. LOVE:

Q. Okay. Are you ready to proceed?

A. I am.
Q. Okay. So you explained the design change itself and the ideas behind the design change. Describe for the jury the types of human testing that Boston Scientific performed with respect to this design change.
A. It did not perform any human testing.
Q. Did they perform any human testing on the heat sealing issue to ensure that it actually did work as they hoped?
A. No. They did not.
Q. Okay. Were there any randomized controlled trials conducted on the Obtryx sling prior to the time it was made available for sale to humans?
A. No.
Q. Was it scientifically feasible at this time in 2002 and 2003 or 2004 to do a randomized controlled trial to assess the safetiness of this product?
A. Absolutely.
Q. Okay. Well, let's talk about some other testing. You mentioned that they did do some testing. And I think we talked about some animal testing. Was there an animal test done with respect to the polypropylene?
A. There was one animal test done, yes.
Q. Okay. Is that the Badylak study?
A. That's correct.
Q. It's not called the Badylak study, but, again, that's the

author's name?

A. That's correct, Dr. Badylak.

MR. LOVE: Your Honor, I'd like to publish Exhibit 877 for the jury.

THE COURT: All right.

(The document was published to the jury.)

MR. LOVE: Do I wait for an objection, if any?

MR. ADAMS: No objection, and the document can be admitted. It's fine with me.

THE COURT: All right. Exhibit 877 will be admitted into evidence without objection.

Mr. Adams, I apologize to you. I thought that he was making reference to the last exhibit when I told him it was okay to publish it. It has been admitted. It can be published at this point.

MR. LOVE: Okay, thank you, ma'am, Your Honor.

(PLAINTIFF EXHIBIT P-877 WAS RECEIVED IN EVIDENCE.)

(The document was published to the jury.)

BY MR. LOVE:

Q. Badylak study, something you reviewed in performing your investigation into this case?

A. Yes, I did.

Q. Okay. Perfect. And let's just kind of walk through it. This will be the first time that the jury has actually seen this. It looks like it's a Boston Scientific animal study?

A. That's correct. It was done under contract at Purdue University for Boston Scientific.
Q. Okay. What's the name of the study, for the jury's benefit? They may not able to see that.
A. Comparison of tissue ingrowth and histology using synthetic meshes in a chronic rabbit subcutaneous implantation model.
Q. Okay. So this is a rabbit study?
A. That's correct.
Q. Okay. And it's done, it looks like the director of that study is a gentleman by the named of Stephen Badylak, or Dr. Stephen Badylak. Are you familiar with Dr. Badylak?
A. I don't know him personally. I'm familiar with him through his testing.
Q. Okay. And this was done, it looks like, January, 2003, so about a year and a half before they began selling this product?
A. That's correct.
Q. Okay. Dr. Badylak, is he an expert in this case for Boston Scientific?
A. That's my understanding, he is, yes.
Q. The jury will get to meet him in a week or so then, good.
All right. Let's talk about this particular study. Let me see if I can work this. Perfect. I just want to run through this, and then I've got a series of questions

before -- just to kind of see where we're at with respect to this study. It says --

MR. ADAMS: Excuse me, Mr. Love, can you tell me which page?

MR. LOVE: I'm sorry. I apologize. I think it is the next page, the second page, 491.

BY MR. LOVE:

Q. All right. It says, "This chronic rabbit implantation experiment was performed to compare the tissue response to implantation of three different kinds of synthetic mesh, Control, Pinnacle Sharp and Pinnacle Melted Cut, at two, six, and 12 weeks." And then it looks like it says, "The rabbits received three subcutaneous abdominal wall implants," and then the overview talks about, "There were 36 adult male and female rabbits that were randomly divided."

So I just -- I kind of want to summarize. First of all, this was a study in rabbits?

A. That's correct.

Q. All right. Where did they put the mesh product in these rabbits?

A. In the abdominal wall.

Q. Where does it go in the human?

A. In the -- underneath the urethra, transvaginally, underneath the urethra --

Q. So the Obtryx sling --

A. -- for the Obtryx sling.
Q. I'm sorry. My apologies. The Obtryx sling is not implanted in the abdominal wall?
A. That's correct, it is not.
Q. Okay. And it looks like -- how long was this study?
A. It was a total of 12 weeks.
Q. Okay. Is that a long-term study from your perspective?
A. For -- it's titled a chronic study. It is, -- in my view, based on my experience, I would not consider this chronic. It would need to be in the rabbit model at least six months, if not nine months, long to be considered a chronic study.
Q. Okay. Now, what does a 12-week study in male rabbits tell us about the long-term complications faced by females?
A. It doesn't. It gives us -- it gives us some information about what may be seen in humans over a period of time. So, again, what it really told us here is that more testing was needed based on the outcome of this study.
Q. And what was the outcome of this study?
A. The outcome of the study was and the reason they have these 36 rabbits, they divided them into three groups of 12, and they sacrificed the animals at two weeks, six weeks and 12 weeks. And they looked at the tissue response at those various time periods to -- and basically, what they saw was a typical inflammatory response to a foreign body in the rabbit.

And at 12 weeks, they saw still a persistent inflammatory reaction ongoing at 12 weeks, but they stopped the study there. So they didn't continue it on to see if it completely dissipated. They -- it was highest at two weeks, and then it changed over time and was reduced at 12 weeks, but it was still persistent.

Q. Okay. As a clinician, what does this persistent inflammatory response tell you needs to be done next?

MR. ADAMS: Your Honor, may we approach?

THE COURT: Yes, sir.

(The following occurred at sidebar.)

MR. ADAMS: This is outside the scope of her report, and it's also outside the scope of her expertise. She said in her report that Boston Scientific only did animal studies. She did not go into the details and criticize the animal studies, which she has now done. She is not a material science expert which is what Dr. Badylak is.

So, one, this is outside her expertise. Two, it's a non-disclosed opinion. I should have objected probably two questions earlier.

MR. LOVE: She's an expert in preclinical studies and designs. This is right in her expertise. Second, this is foundation for her opinion that the Badylak study -- she's not criticizing it. She's saying it had findings that indicated to a clinician like her that additional tests should be done.

Her opinion is they failed to do those proper additional tests.

THE COURT: She needs to get to her opinion. She has stated here with respect to this opinion, when you ask her, which I find is a question asking for the very type of opinion that he's talking about, you ask her, what does a 12-week study in male rabbits tell us about how this device would work in females? And her answer was, it tells us nothing. That is, in fact, a criticism of the study. So it can be interpreted in that way.

MR. LOVE: Okay.

THE COURT: I think that she -- I'm going to limit her to the opinions that are outlined in her report, those which have not been excluded by Judge Goodwin, and if she did not give opinions criticizing this animal study, I am going to exclude those opinions.

MR. LOVE: Okay. This is cited in her opinions to her report and is as a precursor, I will be happy to move on.

THE COURT: I think because she is testifying, Mr. Love, about testing and she is going to criticize the testing which is valid based on the opinion that she gave, she's certainly in a position to testify that that 12-week study told her that more testing was needed.

MR. LOVE: Okay.

THE COURT: But she went somewhat further than that

when she said that it would --

MR. LOVE: Okay.

THE COURT: I think that is at least an implied criticism of testing.

MR. LOVE: Okay.

THE COURT: To that extent, I will preserve the objection -- I sustain your objection and preserve an objection exception for you, Mr. Love.

MR. LOVE: Thank you.

(Sidebar concluded.)

BY MR. LOVE:

Q. Are you ready?

A. Ready.

Q. Let's kind of wrap up the Badylak study. The conclusion was, you identified, I think, persistent inflammation. What does that tell you as a clinician?

A. That tells me that more testing needed to be done, a longer period of testing in animals, but also that that could also mean that in humans, there may be a mild and persistent chronic inflammation that occurs with implantation of the mesh.

MR. ADAMS: Objection, Your Honor.

THE COURT: Objection to that portion of the response is sustained, counsel.

MR. LOVE: Perfect.

MR. ADAMS: And, Your Honor, I move that it be stricken.

THE COURT: I will strike it from the record. The latter part of her answer, Mr. Love.

MR. LOVE: Thank you, Your Honor.

BY MR. LOVE:

Q. Does the Badylak study support your opinion that additional human testing should have been done?

A. Yes, it does.

Q. Okay. Let's talk about the Material Safety Data Sheet. Are you familiar with it?

A. Yes, I am.

Q. Okay. Now, the jury has seen, has heard from a Charles Smith, and he's talked about it, so I don't want to go over or repeat it.

But why is it -- just briefly, why is the Material Safety Data Sheet, as it pertains to polypropylene, relevant to your opinion in this case about testing?

A. It is important to my opinion because of the medical caution statement that is on that Material Safety Data Sheet.

Q. Let's back up a little bit and lay a little bit of foundation.

Do manufacturers of medical devices receive parts or substances from suppliers when developing new products? Is that unusual?

A. No, it's not unusual.
Q. Okay. How do they -- and they then incorporate those products into their device; is that fair?
A. The components, they incorporate into their devices, yes, they --
Q. Okay. And is it standard in the industry for those suppliers to provide safety information regarding component parts where appropriate?
A. That's correct.
Q. Have you seen that over your 40-plus years in working in the medical device industry?
A. Yes, I have.
Q. Okay. And where is this type of information typically maintained by the medical device company if they receive such information?
A. It's maintained in the device records for development of the device.
Q. Okay. Let's talk about the Obtryx sling. Are there component parts for this device that were received by outside suppliers?
A. Yes.
Q. All right. And --
A. Received from outside suppliers, yes.
Q. What component part are we specifically talking about when we're talking about the polypropylene mesh?

A. The polypropylene resin.
Q. And who were they -- who was Boston Scientific receiving this particular resin from during the relevant time period prior to launch?
A. From a company called Phillips Sumika which was a joint venture of Chevron Phillips with another company, Sumitomo Chemical, if I recall correctly was the name of the other company.
Q. Okay. Fair enough.
MR. LOVE: Your Honor, at this time I would like to move for the admission of Exhibit 1004, which I believe would be the fourth tab on your notebook, as well as yours, Mr. Adams.
THE COURT: Objection, counsel?
MR. ADAMS: And, Your Honor, subject to our prior objections.
THE COURT: All right. I overruled or reaffirmed the objections that you have previously made, the rulings to those objections, and admit Exhibit 1004, preserving the defendant's objection and exception.
(DEFENDANT EXHIBIT 1004 WAS RECEIVED IN EVIDENCE.)
(The document was published to the jury.)
BY MR. LOVE:
Q. And with respect to Exhibit 1004, have you had an opportunity to review the January 1st, 2004, MSDS provided by

Chevron Phillips to Boston Scientific?
A. Yes, I have.
Q. And is it relevant to your opinions in this case?
A. Yes, it is.
Q. Okay. And let's take a look at it. And this is something that's not unfamiliar to you or the jury at this point, so I'll kind of just get to the point here.

Okay. The jury has seen the medical application caution here. Why is this important to you as a clinician who helps companies prepare studies to launch new medical devices?
A. This is important because this says that the raw material is not intended for use in permanent implantation in the human body or permanent contact with body fluids or tissues. And what that means to me is that there has been no testing to determine its appropriateness or its fitness for permanent implantation.
Q. Okay. And what does that tell you needs to happen as a clinician?
A. More testing.
Q. Okay. Human testing?
A. Appropriate testing.
Q. Human testing?
A. Human testing, that's correct.
Q. Okay.
A. Animal testing first and then human testing.

Q. Let's talk about what happened after Boston Scientific received this. That's January 28, 2004, correct?
A. That's correct.
Q. All right. And the product began to be made available for sale to humans in August, 2004, right?
A. That's correct.
Q. So we're looking about seven or eight months or so there, right.
A. That's correct.
Q. Okay. After receiving this in January, what specific study did Boston Scientific initiate to ensure that this product was safe?
A. Boston Scientific did not initiate a study.
Q. Did they halt production of the Obtryx sling until studies were completed?
A. No, they did not.
Q. Did they do a press release saying we have received new information?
A. No.
Q. Okay. Now, you've actually looked at a lot of documents, I assume?
A. I have.
Q. Okay. Do you feel like you've done a pretty thorough search?
A. I've done a very thorough search, that's correct.

Q. Okay. Was this the first time that any chemical company was telling Boston Scientific not to use it for permanent implantation, that you're aware of?
A. Yes, that's correct.
Q. What did they do?
A. They did nothing. They kept selling -- well, they marketed the product in August of 2004 without doing any testing to determine the appropriateness of the polypropylene for permanent implantation in the -- as the Obtryx Sling.
Q. Now, if a company like Boston Scientific does not study its products to ensure its safe in humans, what are the potential consequences?
A. Safety risks, not -- that it may not work, as well, may not be effective. But, most importantly, that there may be safety problems with it --
Q. Okay.
A. -- once it is used in humans.
Q. Now, I heard Mr. Adams in opening statement saying that this polypropylene stuff that we're complaining about has been used in different body parts for 55 years. Have you heard that before?
A. Yes, I have.
Q. Okay. Can a product that is safely used in one part of the body automatically be assumed to be safe in all parts of the body?

A. No, it cannot.
Q. Okay. Why not?
A. Well, the ProteGen sling is a perfect example. The ProteGen sling was previously used and was used in vascular grafts as a product called Hemashield, and once it was used in the vaginal application for which Boston Scientific marketed it --

MR. ADAMS: Objection, Your Honor. This is, again, outside the scope and lack of foundation.

THE COURT: Response, counsel?

MR. LOVE: Your Honor, it's one of the things that we need to distinguish, that I presented in opening and what's cited in her report, is that studies that were conducted and completed on other products can't establish that this product is safe, and she's just making that clarification as a clinician that you need to study your own products.

MR. ADAMS: May we approach, Your Honor?

THE COURT: All right.

(The following occurred at sidebar.)

THE COURT: There was an objection to the question about whether or not one could assume that a device that's been used in other parts of the body is safe for all portions. There was an objection, counsel. Next question --

MR. ADAMS: Right. And I appreciate that, Your Honor. My objection is he's far beyond the scope of the

opinion allowed by Judge Goodwin. The opinion allowed by Judge Goodwin was they should have done premarket clinical testing. She's already stated that opinion and the basis. Now for her to start talking about studies and whether those studies justify the use of polypropylene is outside the scope.

THE COURT: Mr. Love?

MR. LOVE: That was my fault because I did miss that.

Her opinion is that part of her investigation, she reviewed all of the available literature and she says you have to. You have to look at studies that are done on other products because they will give you insight into what's appropriate for your product. All I'm establishing is she's saying that looking at other products exclusively doesn't get you the appropriate testing in this product. And so her opinion is perfectly consistent and contained within her report. She's saying look at the universe, but only looking at studies on other products and not this one isn't sufficient as a company.

THE COURT: It would seem to me that she has made that statement.

MR. LOVE: Yes.

MR. ADAMS: Okay.

THE COURT: And so I don't know if you --

MR. LOVE: I'll move on.

THE COURT: All right.

MR. ADAMS: Well, I don't want to keep interrupting either. In the notebook are reports, actual studies that postdate the launch of the Obtryx. There is no reason why she should be able to go into studies that postdate the launch. The sole reason is that --

MR. LOVE: I haven't done that.

MR. ADAMS: Okay.

THE COURT: And that, therefore, is consistent with what the judge has ruled that she's not permitted to do that.

MR. LOVE: Okay.

MR. ADAMS: Okay.

THE COURT: Anything further either of you want to place on the record?

MR. ADAMS: No, Your Honor.

MR. LOVE: No.

MR. ADAMS: Thank you.

(Sidebar concluded.)

BY MR. LOVE:

Q. Okay. Are you ready?

A. I'm ready.

Q. I'm trying to figure out -- I'm trying to wind this down, if I can.

Mid-urethral slings, the Obtryx is a mid-urethral sling?

A. That's correct, it is.

Q. There have been a number of studies done on mid-urethral slings, right?
A. That's correct.
Q. There have been -- half dozen or a dozen or whatever on Obtryx, but a whole bunch on other types of mid-urethral slings; fair?
A. That's correct.
Q. All right. Is it okay for a company like Boston Scientific to rely upon studies done on other products to establish that the Obtryx Sling is safe?

MR. ADAMS: Objection, Your Honor, outside the scope.

THE COURT: That question has been asked and answered prior to you all coming to the bench.

MR. ADAMS: Plus cumulative. I'm sorry.

THE COURT: That objection is sustained.

MR. LOVE: Okay. Fair enough.

BY MR. LOVE:
Q. At the end of the day, I guess just to close this out, what is your opinion as to what the appropriate testing Boston Scientific should have done prior to selling this product to humans?

MR. ADAMS: Objection, Your Honor. This is cumulative.

MR. LOVE: Well, I'm asking for specific times of studies.

THE COURT: I will overrule it at this point, counsel, until I can see where this is going. If you feel the need to interject other objections, I'll address them.

Go ahead, Mr. Love.

THE WITNESS: Boston Scientific should have done additional preclinical testing and then human testing, particularly a randomized controlled clinical trial of an appropriate design prior to marketing this product --

Q. That's --

A. -- for permanent implantation. Sorry.

Q. I appreciate your time today.

A. Thank you.

MR. LOVE: Can I get my Obtryx Sling back from you?

THE WITNESS: Thank you.

THE COURT: Cross examination.

MR. ADAMS: Yes, Your Honor.

(CROSS EXAMINATION OF PEGGY PENCE BY MR. ADAMS:)

Q. Good afternoon, Dr. Pence.

A. Good afternoon.

Q. We have met before, haven't we?

A. We have.

Q. I have some follow-up questions for you. And if we could, could we put those background slides up that you started with?

In your testimony with Mr. Love, you were talking about

your background and work that you do in litigation. Do you recall that?

A. I do.

Q. And you, in fact, are being paid $500 an hour for your work in this case, correct?

A. For my time, that's correct.

Q. And you -- you first began consulting on Boston Scientific litigation about a year and a half ago, two years ago; is that correct?

A. It would have been sometime in 2013, that's correct.

Q. All right. And at least as of August of 2014, you had billed over $300,000 on Boston Scientific matters, correct?

A. That's correct.

Q. And the amount that you've billed since August is now much higher, correct?

A. I haven't billed it yet but there are certainly more hours that have been --

Q. You put on --

A. -- extended.

Q. Okay. You are now up over $500,000, correct?

A. I haven't totaled it. I anticipate that my own time that I've probably spent in total about 500 hours at this point in time on the Obtryx, the Obtryx Sling, Pinnacle Sling, other Boston Scientific products.

Q. And besides you billing out $500 an hour, you also bill

out other individuals at your company at $90 an hour, $150 an hour, and $350 an hour, correct?
A. That is correct.
Q. And now, in this case, I want to go back. With respect to these slides, you had -- when you were talking with Mr. Love, you were talking about the consulting work that you do with other -- these other companies. You mentioned the three different areas: Pharma, bio, and medical, correct?
A. That's correct, medical device.
Q. And the area of litigation support, you had mentioned to Mr. Love that you got into that about five years ago, correct?
A. Five to six years ago, that's correct.
Q. And your income from litigation support has steadily increased since you got into litigation five years ago, correct?
A. That would be correct. It's --
Q. And, in fact, if we go back, when you got in in 2008, your litigation income was about five percent of your company's revenue, correct?
A. I would have to -- for 2008, I really was only contacted towards the end of 2008 and really only began work in 2009.
Q. Okay. Do you disagree with that? I've got a transcript I could show you that your litigation income, you estimated, was about five percent of your revenue in 2008.
A. It would have been no more than that, that's correct.

Q. And then in 2011, litigation income comprised 30 to 50 percent of your company's revenue, correct?
A. That sounds about right. I would have to look back at the actual percentages several years ago to confirm that. That sounds about right.
Q. And recently, in 2014, you've estimated that income from litigation is now 50 to 60 percent of the revenue of your company, correct?
A. Yes. It's variable, depending on whether I'm teaching or what -- what stage of litigation the projects I'm working on are.
Q. Okay. So if we're looking at this chart, and we were trying to figure out what percentage of revenue you make out of testifying in litigation like this, if we draw a line right here, as far as the revenue, 50 to 60 percent comes from your work in litigation support, correct?
A. That would be correct. And it's variable.
Q. And -- now, you've testified in other cases before, correct?
A. Yes, I have.
Q. And you've given testimony against other medical device companies, correct?
A. Yes, I have.
Q. And isn't it true that you have never given testimony on behalf of a medical device company in either a deposition or

at trial like we're here now, correct?
A. If you're limiting it to a deposition or a trial, that's correct.
Q. Again, my question is: Isn't it true you have never given testimony in a deposition or a trial on behalf of a medical device company? Correct?
A. As I said, if you're limiting to that, that is correct.
Q. And with respect to the Obtryx and polypropylene, you've talked a lot about that. Isn't it true that before your assignment in this litigation, you had never done any research into polypropylene?
A. That's correct.
Q. And you had not done research, testing, and evaluation of polypropylene products before you were hired by the plaintiffs in this litigation, correct?
A. That's correct.
Q. And since -- and let's talk about the mechanics.

When you were hired to start learning about polypropylene, you were essentially engaged by one of the plaintiffs' firms at a rate of $500 an hour, correct?
A. For my time, that's correct.
Q. And then what you did is is that you reviewed a variety of documents that came from Boston Scientific, correct?
A. That were produced by Boston Scientific, as well as I mentioned, I did my own independent research as well, my own

reviews of the scientific and medical literature, other types of relevant documents.

Q. And let's just talk about the information from Boston Scientific. You know that Boston Scientific produced documents in this case to plaintiffs' counsel, correct?

A. That's correct.

Q. And you know that you were then supplied or provided a percentage of those documents from plaintiffs' counsel, correct?

A. I wouldn't -- I can't agree with your question just as you've asked it because, yes, I was provided documents, but I also was given access to other documents and requested a number of documents. As a scientist, as I review information, it raises questions, then there are other documents that I need to see in order to answer my questions to do an appropriate investigation. So I repeatedly asked for documents. So I did not -- if you're suggesting that I only reviewed what was provided to me and nothing beyond that, that is inaccurate.

Q. All right. No, but your source of information about documents from Boston Scientific would have to come from plaintiffs' counsel; agreed?

A. Yes, as provided by Boston Scientific.

Q. And when we talk about -- you had given a number of opinions today on -- for example, the testing of -- done by

Dr. Badylak. Now, you know Dr. Badylak is a biomaterials expert, correct?
A. He's in the Department of Biomechanical Engineering.
Q. At what university?
A. Perdue University.
Q. And do you know how many published papers Dr. Badylak has in the area of materials science?
A. I haven't counted them.
Q. Do you have one?
A. No, I don't.
Q. And you're obviously not a bio- -- you're not a biomedical engineer or a materials science expert, correct?
A. No. I have a Ph.D. in toxicology.
Q. I realize that, but you're not a biomaterials expert, correct?
A. That's correct.
Q. And you've never done -- outside of this litigation, you've never been engaged by a company or on your own to research what happens to polypropylene inside the human body, correct?
A. Not for polypropylene specifically, that's correct.
Q. And, obviously, you've never been involved in the design of any kind of polypropylene mesh product or SUI products, correct?
A. That's correct.

Q. Now, let's talk about the history of polypropylene just for a little bit. Mr. Love brought that up.

You know, and Mr. Love brought up, that polypropylene's been used in the body for years, correct?

A. Yes, it has.

Q. It goes back to the 1950s when -- actually, there was an individual, you cited a report in your -- in your report, there was a study done by a Dr. Usher on the use of Marlex polypropylene mesh in the human body, correct?

A. It's -- yes, that's correct.

Q. And Marlex is a specific name of a specific type of polypropylene compound, correct?

A. It's the polypropylene that's used in the Obtryx Sling, yes.

Q. Exactly. The exact same material, the exact same polypropylene compound that Dr. Usher wrote his papers about regarding the use of that compound in the body in the 1950s, is the same compound that Boston Scientific used in the Obtryx, correct?

A. Without comparing how his material was processed versus knowing how the current polypropylene resin is processed, I can't say that it was exactly the same.

Q. Well, now, ma'am, you've talked a lot about the danger of this Marlex polypropylene. Did you not investigate that issue before you came in here to testify to the jury?

A. I didn't investigate it compared to Dr. Usher's -- the product that he used back in the 1950s.
Q. But you've agreed with me that the compound that is used in the Obtryx and that was used back in the '50s in the Usher studies is the Marlex polypropylene compound, correct?
A. I have -- I've not agreed that it's the same product. Over a period of 50 years, there may have been changes in the processing, and without doing that comparison, what the leachables may be from the polypropylene, I can't say if they're identical. They may have the same name but the product may not be the same over a 50-year period.
Q. But you're not willing to tell this jury that -- one way or another whether it's the same compound because you haven't done that research, correct?
MR. LOVE: Objection, Your Honor. If he's going to cross-examine her on the study, certainly, he can make it available, they can find out if it's the same.
MR. ADAMS: I'm just asking her.
THE COURT: I'm going to permit her to answer if she can. Go ahead, please.
BY MR. ADAMS:
Q. Did you do the research to determine whether it's the same compound?
A. I didn't because it doesn't matter to me --
Q. I'm just asking whether you did it or not.

A. -- because it's used in the Obtryx, and the important point is that the Obtryx Sling in its current composition needed to be tested to determine if the Obtryx Sling was appropriate for marketing. Boston Scientific is not marketing the Usher product. It's marketing the Obtryx Sling.

MR. ADAMS: Your Honor, I move to strike everything after "I didn't."

THE COURT: I'm going to overrule that motion, counsel, and I'll address it at the bench at a later time if you all want.

MR. ADAMS: Understood.

BY MR. ADAMS:

Q. Now, let's go back and talk about the use of the particular polypropylene resin by Boston Scientific and Boston Scientific's product. You know that Boston Scientific originally started buying that same polypropylene resin back in 1992, correct?

A. I don't recall the year specifically, but, yes, early '90s, to the best of my recollection.

Q. All right. And, in fact, let me show you a timeline, you've seen this before, for us to work off of. The timeline that we are looking at, Dr. Pence --

MR. ADAMS: Yes. It was the one I used in opening but I'll give you a copy.

BY MR. ADAMS:

Q. Dr. Pence, the timeline that I've handed you will help us -- orient us on the dates. And you've testified and researched the products that use this same Marlex polypropylene, correct?
A. Yes.
Q. And so if we could put up on the screen the timeline. And this is the same one I used in opening.
(The document was published to the jury.)
BY MR. ADAMS:
Q. Now, the -- and we will get into this MSDS sheet. Just so the jury has a reference, the MSDS sheet that Mr. Love asked you some questions about with the medical application caution, which is Exhibit 1004, that medical application caution first came out on January 28th of 2004, correct?
A. That's correct.
Q. And prior to January 28th of 2004, Boston Scientific had been buying the exact same Marlex polypropylene resin from Phillips Sumika, correct?
A. That's correct.
Q. And those purchases go all the way back to 1992 when Boston Scientific was actually selling the Trelex hernia mesh, correct?
A. Yes. I believe they began selling it in 1993, to the best of my recollection.
Q. Okay. And you know that that exact same compound, not

only was it used in Trelex starting in 1992, but it was also used in the Advantage sling, the Lynx sling, in 2002, correct?
A. Yes, it was.
Q. And then we have its use in the Obtryx in -- which was launched on April 14th of 2004, correct?
A. That's correct.
Q. And then later used in the Solyx, which was launched on August 27th of 2008, correct?
A. Yes.
Q. And, by the way, both the Advantage, the Lynx, the Obtryx and the Solyx, those are products that are still being sold today, correct?
A. That's -- actually, I'm not certain about the Obtryx. According to deposition testimony that I've read -- I'm not sure what deposition testimony that I've read -- it is still on the market, but I was recently checking the website for Boston Scientific and it does not show Obtryx. It shows Obtryx II as one of the five available slings on the market.
Q. All right. You don't know one way or another whether Obtryx is still being sold; fair?
A. Well, what I'm saying is there is a disconnect between what's on the website that I accessed recently and the most recent deposition testimony to which I have access.
Q. You know the Advantage and the Lynx and the Solyx are also being sold, correct?

A. Yes.
Q. All right. Now, and the chemical composition of this polypropylene has remained the same from '92 all the way to the present date, correct?
A. I can't speak to the present day because my understanding is that --
Q. I will rephrase the question.
A. -- Boston Scientific is no longer --
THE COURT: Just a second. The court reporter can't take down both of you. Mr. Adams, I'm going to let you ask your question. I want you to listen carefully, Doctor, and answer it. Go ahead, please.
MR. ADAMS: And I'll rephrase the question.
BY MR. ADAMS:
Q. You'll agree with me that the chemical composition of the Marlex polypropylene resin remained the same from the time Boston Scientific purchased it for the Trelex all the way through the time the Obtryx launched in April of 2004, correct?
A. The Obtryx actually launched in August of 2004, but, other than that, yes, the answer to your question is yes.
Q. And we know that prior to -- again, prior to January of 2004, there was never any MSDS medical caution like what we've seen in Exhibit 1004, correct?
A. That's correct.

Q. So the exact same material stayed the same and the only thing that changed was the addition of the medical application caution, correct?
A. Would you repeat that question?
Q. The material stayed the same; the only difference was the addition of the language of the medical application caution, correct?
A. The Marlex mesh sold by the -- Phillips Sumika stayed the same, to the best of my knowledge.
Q. All right. And this Material Safety Data Sheet, now, you know that a Material Safety Data Sheet is put out pursuant to OSHA regulations, correct?
A. That's correct.
Q. And OSHA stands for what?
A. Occupational Safety and Hazards --
Q. Administration?
A. Administration. Thank you.
Q. You did pretty well.
And, basically, what OSHA does is OSHA's job is to promulgate rules with respect to workers that will handle raw materials like polypropylene pellets, correct?
MR. LOVE: Objection.
THE WITNESS: For that --
THE COURT: I'm sorry.
MR. LOVE: Objection to proper foundation.

THE COURT: Counsel?

MR. ADAMS: I'm asking --

THE COURT: Do you understand the objection?

MR. ADAMS: I don't.

THE COURT: Mr. Love? Improper foundation? I assume you all want to come to the bench.

(The following occurred at sidebar.)

MR. LOVE: He's laying a foundation about what OSHA requires, without any foundation, without asking if she's familiar with them. I mean, he's offering expert testimony as a lawyer.

MR. ADAMS: I'm just asking if this is done pursuant to OSHA regulations, which she's answered OSHA is responsible for protecting workers. I'm not going to go into that the FDA is responsible because I can't do it, but I can definitely show that OSHA promulgates rules for MSDSs.

THE COURT: I think Mr. Love's objection, if I understand, is that there has been no real foundation laid as to her knowledge about that. And I think if you lay that, your objection will be moot, and if I don't understand it, Mr. Love, I want you to let me know.

MR. LOVE: I think that's exactly right. What he's trying to suggest is those OSHA regs are for protection of workers and that's not the case. That's part of the reason they exist. So if he wants to lay the foundation and say what

the purpose of the OSHA regs are, to protect end users which could be workers and could be medical device companies, that's appropriate.

THE COURT: Well, more importantly, neither of you testify. Now, she has the requisite knowledge to answer that question so let's go there. I sustain the objection to the lack of foundation, preserving the objection and exception.

MR. ADAMS: I'll go back and try it again.

(Sidebar concluded.)

BY MR. ADAMS:

Q. Dr. Pence, let me go back to where I was.

Did you review the OSHA regulations concerning what OSHA specifies must be contained within a Material Safety Data Sheet as part of your work in this case?

A. Yes, I have.

Q. All right. And you know that OSHA has specific regulations concerning what must be set forth in the various sections of a Material Safety Data Sheet, correct?

A. Yes.

Q. And the hazards to humans must be set forth in Section 3 of document 1004 which is called the Hazards Indication Section, correct?

A. If you'd like -- I don't recall the section by heart. If you'd like to show it to me, I would be happy to look at it.

Q. Certainly.

A. But I know that it does specify that in a particular section, yes.

Q. And if we have it -- you can put your document up on the screen. This is 1004. You'll need to switch over.

And if we could turn to the next page within this document. Do you not have the full document loaded?

MR. LOVE: I have it handy if you want it.

MR. ADAMS: That would be fine. Do you have an extra copy? Thank you.

BY MR. ADAMS:

Q. Dr. Pence, the jury will have this in evidence later and I don't want to belabor the issue, but I'm handing you Exhibit 1004, correct?

A. Yes.

Q. And 1004 is the Material Safety Data Sheet that contains the medical application caution, correct?

A. Yes, it is.

Q. And you know that under the OSHA regulations, under Section 3 of that document, you must identify hazards associated with the product, correct?

A. Correct.

Q. And under the hazards identification, there does not contain any information regarding that -- the statement that this product should not be used in medical applications or implanted in the human body, correct?

A. Not in that section, that's correct.
Q. And with respect to this Material Safety Data Sheet, you are aware that the corporate representative of Phillips Sumika has been deposed in this matter, correct?
A. I am. I've read the deposition.
Q. And you, as part of your work, not only did you look at documents, but you looked and read deposition testimony, correct?
A. That's correct.
Q. And you understand that that deposition was a -- what's called a corporate designee deposition under Rule 30(b)(6), correct?
A. Yes, I do understand that.
Q. And under that rule, that company was commanded to bring to the deposition any scientific studies or data that supports the language in that medical application caution, correct?
A. Yes.
Q. And you know that Phillips Sumika, when they testified in that deposition through an individual named Frank "Z" -- he's got a hard name.
A. Yes, he does.
Q. They produced no scientific studies and no other studies to establish that they had a basis for adding that medical application caution, correct?
A. To the best of my recollection, the deposition testimony

was that he did not know the reason studies were not done but that the fact that studies were not done did not mean that there was not a scientific basis.

Q. Well, ma'am, and the jury will see this. The individual was not aware of any scientific basis to support that statement, correct?

A. To the best of my knowledge, that is correct.

Q. And the individual and the company who was commanded to produce any scientific studies or any basis for that statement produced zero documents at that deposition, correct?

A. To the best of my recollection, that's correct. But if you have his deposition, I would be happy to take a look at it and refresh my memory because there was some very specific questioning along those lines --

Q. And the jury will see that.

A. -- and he was very careful to respond, as I mentioned, that he really didn't know the reason for that statement.

Q. And, ma'am, you know that attached to the deposition, there were no studies or documents to support the statement, correct?

A. That were provided at that deposition.

Q. All right. And --

A. That's correct.

Q. In fact, from your review of information from Boston Scientific --

MR. ADAMS: Can we put our timeline back up? We need to change the box.

BY MR. ADAMS:

Q. Okay. From your review of the Boston Scientific information, after Phillips Sumika included this language in the MSDS that had never been there before, you know that people at Boston Scientific such as Doreen Rao investigated as to why that language was included, correct?

A. I know she was -- yes, she was deposed about that, that's correct.

Q. And, in fact, Doreen Rao has testified that she learned from Phillips Sumika that there was no scientific basis for the language and it was simply added as legal language, correct?

A. To the best of my recollection, there is also testimony -- if you have her deposition, I would be happy to refresh my memory -- but, to the best of my recollection, there is also testimony from Doreen Rao that that statement could not be taken as not having meaning.

Q. But you know that she testified that one of the reasons she was provided by Phillips Sumika for the inclusion of the language was for legal reasons, correct?

A. I don't recall that specific testimony. If you have it in front of you and would like to show it to me, I will be happy to refresh my memory.

Q. The jury will hear from Ms. Rao on that issue.

Let's talk about -- it's a good sign when I'm turning all these pages, Dr. Pence.

Let's talk about your testimony regarding premarket clinical studies, and you gave some testimony regarding the detanged edges on the Obtryx and the Advantage mesh, correct?

A. Yes.

Q. And you, ma'am, know that that product, the product which is the Obtryx and the Advantage, those have been found to be substantially equivalent to other meshes that were on the market --

MR. LOVE: Objection, Your Honor. May we approach?

THE COURT: Yes, sir.

(The following occurred at sidebar.)

THE COURT: Okay, Mr. Love.

MR. LOVE: This has specifically been excluded. He's just carefully -- he's not using clearance, he's using substantial equivalence to suggest that it was being cleared and/or approved and safe. This is what 510(k) process is. It is substantial equivalence. Judge Goodwin has consistently said this is off base.

MR. ADAMS: He said that I can't refer to the FDA but I'm not referring to the FDA. I'm entitled to say that they have found to be substantially equivalent to other products.

MR. LOVE: That's not --

THE COURT: Be found by who, Mr. Adams?

MR. ADAMS: I can simply say a regulatory body.

MR. LOVE: This is the whole reason why he kept it out. Judge Goodwin has said substantial equivalence doesn't equal safety. The 510(k) process doesn't do that.

MR. ADAMS: Okay. The problem that I have is she created the inference that our mesh is somehow different than the other meshes. That's been found to be substantially equivalent by the government. I can rephrase it and just use -- I didn't even say what entity but I can just say regulatory body.

THE COURT: Give me your question, Mr. Adams.

MR. ADAMS: You would agree that the Obtryx has been found to be substantially equivalent to other meshes on the market, correct?

MR. LOVE: This is back-dooring the FDA approval process.

THE COURT: All right. I'm going to overrule the objection. There is nothing in his question that would indicate that it was substantially similar to either such devices on the market and that it's been proved by anyone, or including the FDA, that it is substantially similar to other devices that are currently on the market. Because of the phrasing of the question, I don't think it it's violative of the order. It's violative to you because you know what the

arguments were. The jury has no idea about that. So, again, I don't think it brings any -- any proof about regulatory agencies.

MR. LOVE: Okay.

THE COURT: I murdered that statement.

My point is this: As the question has been phrased by Mr. Adams, I do not believe it brings into play any approval or non-approval by any regulatory agency. It does to the lawyers because they know what the pretrial arguments were, but to the jury it doesn't, and so I don't think it runs afoul of the Court's order.

MR. LOVE: Can I ask you to the extent -- I just want to make sure we're clear. There is no second question saying by whom it wasn't found to be substantially equivalent?

THE COURT: Mr. Adams wouldn't do that.

MR. ADAMS: No.

MR. LOVE: Fair enough.

(Sidebar concluded.)

BY MR. ADAMS:

Q. May it please the Court, back to my question, Dr. Pence.

You know -- you would agree with me that the Obtryx mesh has been found to be substantially equivalent to other meshes on the market prior to the time that it launched, correct?

A. Yes, on the basis of bench and biocompatibility testing

only.
Q. And not only on the basis of that, but -- you know that an entity outside of Boston Scientific has made that determination, correct?
MR. LOVE: Objection, Your Honor.
THE COURT: That objection is sustained.
MR. LOVE: Thank you.
MR. ADAMS: All right.
THE COURT: And -- I'm sorry. Go ahead.
BY MR. ADAMS:
Q. And -- now, Dr. Pence, with respect to the testing, the premarket testing on the Obtryx, you would agree with me that there are a number of devices that are in the class of mid-urethral slings with the Obtryx, correct?
A. That's correct.
Q. And, in fact, the last time we talked, I think you indicated that you had counted and there are approximately 62 commercialized mid-urethral slings, correct?
A. At least, yes, correct.
Q. And you realize that out of those 62 commercialized mid-urethral slings, a very high percentage of those products were never tested in humans prior to being put on the market, correct?
A. Yes. And that has been a criticism of that, of those -- of the development of those slings, I should say.

Q. And so, for example, you know that the vast majority of the mid-urethral slings that are on the market today were never subject to any randomized controlled trials prior to the time that they were put on the market; agreed?
A. Yes, that is correct.
Q. And so with respect to the industry standards, the industry standards really refer to what the majority of the industry is doing with respect to their products, correct?
A. The industry standards apply -- they're set up by -- you referred earlier to -- to other bodies and substantial equivalence. Industry standards are -- are, in part, determined by companies.
Q. Right. And the vast majority, probably 95 percent of the mid-urethral slings that are not tested before they are put on the market, they would certainly violate your standard, your personal standard, correct?
A. Yes, they would. It's not my personal standard. It's a standard based on over 40 years of experience in product development, with the primary focus of patient safety.
Q. And of those 62 products, 95 percent or more which are not tested before they are put on the market, they are all being lawfully sold in the United States, correct?
A. Yes. And we're seeing major complications arising with them as well.
Q. Move to strike everything after "yes," Your Honor.

THE COURT: That motion is granted, in terms of how the question was phrased.

BY MR. ADAMS:

Q. Now, Dr. Pence, I believe in your report, you had referred to -- with respect to your opinions that premarket testing should have been done, you had referred to some guidelines that were put out by the Scottish National Institute of Health, correct? Do you recall that?

MR. LOVE: Objection, Your Honor. This exceeds the scope of direct examination. It's kind of erratic, I'm not sure where he's going.

THE COURT: Any response to the objection, counsel?

MR. ADAMS: No, Your Honor. I will --

THE COURT: Withdraw?

MR. ADAMS: I will withdraw that.

THE COURT: All right.

BY MR. ADAMS:

Q. And, Dr. Pence, you had talked about the safety of polypropylene in the body in your testimony that you gave when discussing that with Mr. Love. Do you recall that?

A. Yes.

Q. And you're aware of the position statement from January of 2014 by the entity known as AUGS, correct?

A. Yes, I am.

Q. And I'm going to hand you what has been marked as --

MR. ADAMS: May I approach, Your Honor?

THE COURT: Yes, sir.

MR. ADAMS: I'm going to hand you what has been marked as Exhibit 1230.

BY MR. ADAMS:

Q. Now, you recognize material put out by -- in the *Journal of Female Pelvic Medicine and Reconstructive Surgery* as information that is a reliable and authoritative, correct?

A. Correct.

Q. And, in fact, you've cited a number of different studies from that journal in your report, correct?

A. Correct.

MR. ADAMS: And if we can -- if we can put up Exhibit 1230, Your Honor, just for the record, the -- I'm using this as a learned treatise under 803(18).

MR. LOVE: And, Your Honor, I would object on the basis that it's an editorial that was written by consultants for Boston Scientific and done for the purposes of litigation.

MR. ADAMS: And, Your Honor, it is published in a journal and counsel's statement is not accurate. But it has been recognized as reliable authority, it's published in the journal, and so I believe I'm entitled to use it under 803(18).

THE COURT: Let me see it, please.

MR. ADAMS: I will.

THE COURT: Mr. Love, let me bring you to the bench.

MR. LOVE: Sure.

(The following occurred at sidebar.)

MR. ADAMS: Your Honor, first of all, just for reference, this could be confirmed with Kate. This document has been allowed by Judge Goodwin to be used in prior trials under 803(18) after the foundation has been laid that it's reliable and it's authoritative. That's why I asked her those questions.

And then, secondly -- and my understanding by reading the transcripts and talking to people is that when he would allow the use of a learned treatise, you can publish it to the jury. The document definitely is not admitted into evidence, but I can read to her certain things.

And then the other thing that I would note is that I would appreciate it if speaking objections, like his reference to the Boston Scientific paid consultant on this document, would be made at the bench because I don't think that is an appropriate objection.

THE COURT: I understand all that you have offered with respect to how the learned treatise is to be used. My issue, at least initially, is to make that determination. You're saying that this is a document that was prepared for Boston Scientific?

MR. LOVE: A couple of things. One, it's an

editorial. It's not a scientific paper by any stretch of the imagination. These authors here are all consultants to Boston Scientific, Ethicon or other manufacturers, and they specifically testified it was done for litigation purposes. And, second, this has FDA all over it. If it's not properly redacted --

MR. ADAMS: I redacted it. I redacted it. That's why there are gaps in that, Your Honor.

THE COURT: I'm sorry. I will let you finish.

MR. LOVE: And it's not an authoritative source. It's an editorial. It's not based upon science.

THE COURT: Mr. Adams, you indicate that Judge Goodwin has allowed this to come in as a learned treatise.

MR. ADAMS: Yes.

THE COURT: In prior cases?

MR. ADAMS: Yes.

THE COURT: And that's consistent with your recollection?

MR. ADAMS: It is.

THE COURT: Mr. --

MR. LOVE: I don't have a recollection.

MR. ADAMS: And, in fact, they filed a motion in limine on the industry statements which he denied as well. And then I redacted the document because I know, from reading the transcript, that Judge Goodwin demanded that documents be

redacted with the FDA information.

THE COURT: Where was this published? In what journal?

MR. ADAMS: The journal down below, Your Honor. It is the *Female Pelvic Medicine and Reconstruction Surgery Journal*.

THE COURT: All right. Anything further?

MR. LOVE: Actually, yes. He is going to use it to suggest that it's a reliable authoritative source and there is no scientific basis for it. It is simply the opinions in an editorial of five consultants for the mesh industry.

THE COURT: This document has been referred to as 1230. I have reviewed it. I think that, Mr. Love, your characterization of it as an editorial is correct. However, it appears to be part of a *Journal of Female Pelvic Medicine and Reconstructive Surgery,* and it's titled at the bottom justification for the position statement. I'm going to permit it under Rule 803.

I will be very candid with the parties that I permitted it, in part, because I want to try and make sure that during the course of this trial, that I follow the judge's rulings in terms of the global fairness in all of the cases in which he's going to try. So I'm going to permit it, preserving the plaintiffs' objection and exception to it as a learned treatise.

MR. ADAMS: Thank you.

(Sidebar concluded.)

MR. ADAMS: Okay, Dr. Pence, let's go through this and this is Exhibit 1230. If we could put that up on the screen.

(The document was published to the jury.)

THE COURT: Mr. Adams, let me interrupt you. Is this a good place that I could give the jury a recess?

MR. ADAMS: That would be fine, Your Honor.

THE COURT: All right. Ladies and gentlemen, I'm going to give you a recess. While you're out, do not discuss this case among yourselves or permit anyone to discuss it with you or in your presence. You have been in the jury box about two hours now. We will return to the courtroom at approximately 10 minutes till the hour.

COURT SERVICES OFFICER: All rise.

(The Jury left the courtroom at 3:34 p.m.)

(A recess was taken at 3:34 p.m.)

THE COURT: I'm sorry. I was told the jury was here. Would you get them, please.

COURT SECURITY OFFICER: Yes, ma'am.

(Jury entered the courtroom at 3:53 p.m.)

THE COURT: You all be seated, ladies and gentlemen.

MR. ADAMS: May it please the Court.

THE COURT: Mr. Adams, yes, sir.

BY MR. ADAMS:

Q. Dr. Pence, are you ready?

A. Yes, I am.

Q. Before we took our break we were looking at the statement from the American Urogynecologic Society. You're familiar with that group; correct?

A. Yes, I am. I'm a member.

Q. And down at the bottom it says that this is put out by that society and also in conjunction with another group or organization for physicians. It's called the Society of Urodynamics Female Pelvic Medicine and Urogenital Reconstruction. Correct?

A. SUFU, correct, for short.

Q. It's much easier to say SUFU. So, we can see that these are both professional organizations that many doctors in the United States and, in fact, worldwide belong to; correct?

A. Correct.

Q. And this position statement up at the top, we concede that it says -- if we could blow up that portion, it says, "The polypropylene mesh mid-urethral sling --" and let me stop there. The Obtryx is a polypropylene mid-urethral sling; correct?

A. That's correct.

Q. It says, "The polypropylene mesh mid-urethral sling is the recognized worldwide standard of care for the surgical

treatment of stress urinary incontinence. The procedure is safe, effective, and has improved the quality of life for millions of women."

Did I read that directly?

A. You read that statement correctly, yes.

Q. And then when we go down to -- you had voiced some opinions regarding polypropylene. Underneath the section regarding justification for the position statement, it says, "Polypropylene material is safe and effective as a surgical implant. Polypropylene material has been used in most surgical specialties including general surgery, cardiovascular surgery, transplant surgery, ophthalmology --" help me with the pronunciation of this next word.

A. Otolaryngology.

Q. And what is that?

A. Ear, nose, and threat.

Q. All right. "It's been also used in gynecology and urology for more than five decades in millions of patients in the United States and the world." Did I read that correctly?

A. Yes, but you eliminated the parenthetical "personal communication with manufacturers of polypropylene suture and mesh."

Q. Right. And that's right up here. And, in fact, you have seen before -- and I showed the jury a diagram of the human body showing that polypropylene today and going back into the

1950s is used in various portions all over the body; correct?
A. That's correct.
Q. And that's what that statement just said; correct?
A. Yes.
Q. It's been used for five decades all over the parts of the body; correct?
A. Yes, in one form or another, that's correct.
Q. And the next sentence, it says, "An isolated thread --" "As an isolated thread, polypropylene --" if we can blow that up, the next section just so the jury can read along.

Okay. It says, "As an isolated thread, polypropylene is widely used and durable suture material used in a broad range of sizes and applications. As a knitted material, polypropylene mesh is the consensus graft material for augmenting hernia repairs in a number of areas in the body and has significantly and favorably impacted the field of hernia surgery. As a knitted implant for the surgical treatment of SUI, macroporous, monofilament, lightweight polypropylene has demonstrated long-term durability, safety, and efficacy up to 17 years."

Did I read that correctly?

A. You read that correctly, but the last statement I would like to clarify is based on a single study. And that single --
Q. My question was: Did I read that correctly?

A. You read it correctly.
Q. Okay. And when it talks about macroporous monofilament polypropylene, that is a term of art to use to describe particular types of polypropylene; correct?
A. That's correct.
Q. And you know that the polypropylene mesh used in the Obtryx and the Advantage is macroporous monofilament polypropylene mesh; correct?
A. It's described as macroporous and monofilament, correct.
Q. The next section of this document, if we could blow that up, it says, "The monofilament polypropylene mesh mid-urethral sling is the most extensively studied anti-incontinence procedure in history. A broad evidence base including high quality scientific studies in medical journals in the United States and the world supports the use of the mid-urethral sling as a treatment for stress urinary incontinence. There are greater than 2,000 publications in the scientific literature describing the mid-urethral sling in the treatment of SUI."
Did I read that correctly?
A. Yes.
Q. The last sentence it says, "No other surgical treatment of SUI before or since has been subject to such extensive investigation."
Did I read that correctly?

A. You read that correctly, yes.
Q. And then the next paragraph, and we're almost done, the next paragraph is entitled, "Polypropylene mesh mid-urethral slings are the standard of care for the surgical treatment of stress urinary incontinence and represent a great advance in the treatment of this condition for our patients.
"Since the publication of numerous level one randomized comparative trials, the mid-urethral sling has become the most common surgical procedure for the treatment of SUI in the United States and the developed world."
Did I read that correctly?
A. You read that correctly.
Q. You know that the Obtryx and the Obtryx II not only are sold lawfully in the United States, but are sold around the world; correct?
A. They are.
Q. It goes on to say, "This procedure has essentially replaced open and transvaginal suspension surgeries for uncomplicated SUIs. There has been more than 100 surgical procedures developed for the management of SUI and there is now adequate evidence that the mid-urethral sling is associated with less pain, shorter hospitalization, faster return to usual activities, and reduced costs as compared with historic options that have been used to treat SUI over the past century."

Did I read that correctly?
A. Yes, you read that correctly.
Q. Now, as part of your research, you looked into the historic options, the surgical options that are available to women if they decide -- or in conjunction with their doctors if they decide that they don't want to use a mid-urethral sling. Correct?
A. That's correct, I did.
Q. For example, one of the procedures that can be done is the Burch procedure; correct?
A. That's correct.
Q. Another procedure that can be done is what's called the MMK procedure; correct?
A. That's correct.
MR. LOVE: Your Honor, objection. This is beyond the scope of direct examination. He's talking about alternative treatments which she clearly didn't testify about.
THE COURT: That objection is sustained, Mr. Adams.
BY MR. ADAMS:
Q. All right. Let's go back to this position statement and finish it out. Down at the bottom it says, "More than three million mid-urethral slings have been placed worldwide and a recent survey indicates that these procedures are used by more than 99 percent of the AUGS members."

Did I read that correctly?

A. Yes, you did.

Q. And then finally under the Conclusions, if we could go to that section and blow up that paragraph, it says, "The polypropylene mid-urethral sling has helped millions of women with SUI regain control of their lives by undergoing a simple out-patient procedure that allows them to return to daily life very quickly. With its acknowledged safety and efficacy, it has created an environment for a much larger number of women to have access to treatment. In the past, concerns over failure and invasiveness of surgery caused a substantial percent of incontinent women to live without treatment."

The last sentence says, "This procedure is probably the most important advancement in the treatment of SUI in the last 50 years and has the full support of our organizations, which are dedicated to improving the lives of women with urinary incontinence."

Did I read that correctly?

A. Yes, you did.

Q. Now, on the first page of this study, it has the list of the individuals that were involved in drafting this statement. Do you see that at the top?

A. Yes, I do, but a clarification. This is not a study. This is an editorial.

Q. Editorial, fair enough. And the individuals involved are

Charles Nager, Paul Tulikangas, Dennis Miller, Eric Rovner, and Howard Goldman; correct?

A. Yes.

Q. And if we look at the back page of this document, there is a disclosure on there -- if we can blow up the position statement box down here, right here. There is a disclosure that one of the persons on the position statement, Dr. Nager, is a principal investigator in the NICHD and NIH Pelvic Floor Disorders Network which is conducting a recommended randomized trial involving transvaginal mesh for prolapse.

It goes on to say, "The NICHD/NIH through a public private cooperative arrangement has received partial financial support from Boston Scientific Corporation for this study." Correct?

A. That's correct.

Q. And then it goes on to say Dennis Miller receives consulting fees and royalties from Boston Scientific for prolapse mesh; correct?

A. That's correct.

Q. And then it goes on to say that the other individuals who are listed on the front of the editorial, Dr. Tulikangas, Dr. Rovner, Dr. Goldman, have no disclosures; correct?

A. That's correct.

Q. You're not aware of any association of those individuals with any medical device companies; correct?

A. I haven't explored those three individuals to see what other, what other connections they might have.
Q. And this editorial statement was approved by the Board of Directors of AUGS; correct?
A. Yes, many of whom do have an association with industry.
Q. And, in fact, there are a number of other industry groups that have put out and adopted this same statement; correct?
A. I'm not -- I don't know which organizations you're referring to.
Q. Well, were you aware that the Society of Gynecologic Surgeons also have a similar position statement?
A. I vaguely recall that, but I don't remember it specifically. If you have it, I would be happy to take a look at it. I have a number of comments about this position statement I would be happy to offer, though.
Q. Did you, did you look to see whether this statement has also been adopted by the European Association of Urology?
A. No, I didn't, not the European association.
Q. What about -- are you aware of a similar position statement by the Royal Australian and New Zealand College of Obstetricians and Gynecologists?
A. No.
Q. Were you aware of the fact that this statement, or a similar statement has been adopted by the Society of Obstetrics and Gynecology of Canada?

A. I believe I recall that. However, I'd have to read those statements to see --

Q. And you're not here to --

A. -- what differences there are.

MR. LOVE: Objection, Your Honor, if he could let the witness finish her answer.

THE COURT: She does need to finish her answer before you start the next question, Mr. Adams.

MR. ADAMS: Yes, ma'am.

THE COURT: Ma'am, start and repeat your answer, please. I didn't hear it.

THE WITNESS: Okay. Thank you, Your Honor.

What I said was in order to say whether or not those position statements are similar, I would need to compare them because there can be sentences in those that may make a substantial difference or have qualifiers or cautionary remarks.

BY MR. ADAMS:

Q. Now, you mentioned connection to industry in one of your responses dealing with this AUGS statement; correct?

A. Yes.

Q. Now, in these other organizations that have adopted the same or similar statements, you're not aware of any connection to industry in those organizations; correct?

A. I can't answer your question because I haven't looked at the authors of those documents and determined whether or not they have industry connections.
Q. Let's talk a little bit about the ProteGen product. The ProteGen product was put out by Microvasive in what year, ma'am?
A. 1996.
Q. And what was Microvasive?
A. It was a part of Boston Scientific if I recall correctly.
Q. And do you know when Boston Scientific actually purchased Microvasive?
A. I don't recall the year it purchased it, no.
Q. And the ProteGen, as the jury has heard, was voluntarily removed from the market by Boston Scientific in 1999; correct?
A. It was a recall, that's correct.
Q. And let's talk about that product. Now, the Obtryx we've already established is a macroporous monofilament mesh; correct?
A. It's described as macroporous. It is a monofilament mesh, yes.
Q. And the ProteGen, what was the structure or the compound of that material made out of?
A. It was a polyester mesh with a bovine, bovine collagen in it as well.
Q. And it was also a woven multifilament mesh; correct?

A. To the best of my recollection, that's correct.
Q. And with respect to structures, the Obtryx differs because it is a single-knit monofilament; correct?
A. It is a knitted monofilament mesh, correct.
Q. And with respect to --
A. Polypropylene.
Q. -- the actual material, you've already agreed with me that the ProteGen was polyester; correct?
A. Yes.
Q. And the Obtryx is polypropylene; correct?
A. Yes.
Q. Did you research the history of how many different types of medical devices were on the market prior to the ProteGen that were made out of polyester?
A. I didn't do a tabulation of how many were on there --
Q. Were any?
A. -- on the market. There are -- with reference to the years, I don't recall. There certainly are other tests on polyester meshes. I don't recall the timing of the marketing of other polyester meshes.
Q. And you're aware that -- you say that the ProteGen was actually bovine collagen covered; correct?
A. Yes.
Q. And the actual process was is that there was pressure injected bovine collagen onto the polyester woven

multifilament; correct?
A. That's correct.
Q. And prior to the ProteGen, did your research determine whether there were any other woven multifilament polyester products that had bovine injected collagen on them in the use in the marketplace?
A. Prior to the ProteGen?
Q. Yes.
A. I didn't look at that question specifically.
Q. So, you don't know whether -- when people were originally designing the ProteGen whether they had any history at all to go on concerning the biocompatibility of bovine collagen coated polyester; correct?
A. The point is that it was a different mesh. And as testified --
Q. No, my question, ma'am, if you could answer my question.
A. I'm trying to.
Q. All right. Let me rephrase it. My simple question is you don't know whether there were any products on the marketplace prior to the ProteGen that were made of polyester that were bovine collagen coated; correct?
A. I don't know that specifically, that's correct.
Q. And, now, the ProteGen product, that product, how was it anchored inside a woman's body?
A. To the best of my recollection, I think it may have been

sutured. I don't recall definitely. If you have information, I'd be happy to look at it and refresh my memory.

Q. Let me try to refresh your memory this way. Do you recall that the ProteGen device actually used what is referred to as bone anchor?

A. The bone anchors, yes, that's correct.

Q. And bone anchors --

A. I do recall now.

Q. There's not a single -- in these studies and the position statements that talk about the mid-urethral sling being the gold standard, there's not a single one of those devices that use bone anchors like what was used in the ProteGen; correct?

A. That is correct.

Q. Now, you've given some testimony on ISO standards. And you'll agree with me, and I think you've agreed with me in the past, that the mesh used with the Obtryx passed all the ISO biocompatibility standards; correct?

A. I would not go as far as to say as all the ISO biocompatibility standards. There were a select number of biocompatibility tests that were done, as I mentioned, for the Trelex mesh back in 1992, '93 that were the basis on which -- for biocompatibility on which Boston Scientific marketed the Obtryx sling over 10 years later, 11 or 12 years later.

Q. And let's look at the ISO standards. And you're familiar with the ISO standard --

A. Yes, I am.
Q. -- 10993-1. I'm going to hand you what has been marked as 1059. And 1059 is a collection of the international standard which is referred to as ISO 10993-1. Correct?
A. That's correct.
Q. And, obviously, you recognize this to be the actual standard that we've been referring to. And you recognize that this is a reliable standard from an authoritative document?
A. It's part one of the standard.
Q. If we could put the standard up just so the jury understands. These standards, we talk about compliance with ISO.

THE COURT: Counsel, is that something that has been admitted into evidence?

MR. ADAMS: No, and I would rely upon it as a learned treatise.

MR. LOVE: Your Honor, with respect to my objection, I would object. This is well beyond the scope of my direct examination.

THE COURT: It is well beyond the scope of direct examination and I will sustain that objection. And I'm going to ask you all again not to put anything up on that screen for the jury until I admit it into evidence.

MR. ADAMS: Will do, Your Honor. I thought I had laid the foundation for authoritative treatise. And I believe

that Mr. Love did discuss biocompatibility testing which are done pursuant to the standard. That's why I was going into it. So, it was within the scope.

THE COURT: I think that we're far beyond testing and I'm going to sustain the objection.

MR. ADAMS: Understood, Your Honor. I'll move on.

THE COURT: They made every effort on direct examination to limit her testimony to her opinion with respect to testing and I think that's where we need to stay for cross.

MR. ADAMS: Certainly, Your Honor.

BY MR. ADAMS:

Q. Let's move on from that, Dr. Pence, to the last series of questions. Did you review any of the depositions of the doctors who actually implanted the Obtryx in any of the four ladies that are involved in this case?

A. No, I did not.

Q. And, so, you don't know what their personal experience has been concerning the safety and effectiveness of the Obtryx that they've observed in their practice; correct?

MR. LOVE: Objection again, Your Honor, beyond the scope of her testimony. She's not a medical doctor, nor is she commenting on their standard of care or what they do or don't do.

THE COURT: And I sustain that objection.

MR. ADAMS: All right.

BY MR. ADAMS:

Q. No other questions, Dr. Pence. Thank you.

A. Thank you.

THE COURT: Is there redirect of this witness?

MR. LOVE: It will be brief, five, ten minutes tops.

THE COURT: You promise?

MR. LOVE: I promise. May I proceed, Your Honor?

THE COURT: Yes, sir.

REDIRECT EXAMINATION BY MR. LOVE:

Q. Hello again.

A. Hello again.

Q. May we bring up Exhibit 1004, the MSDS. Just a few quick questions I want to jump around. I just want to make sure that we're on the same page as to some topics that were covered in the cross-examination.

A. Okay.

Q. Let's go back to ProteGen real quick. What did Boston Scientific conclude internally with respect to human testing on future sling materials --

A. That --

Q. -- based upon the withdrawal of the ProteGen product?

A. That human testing needed to be done to ensure the safety of a product prior to marketing.

Q. Okay. Whether it's polypropylene or some other sling,

Boston Scientific concluded that with respect to this company, we're going to what?

MR. ADAMS: Objection, Your Honor. This is leading.

BY MR. LOVE:

Q. What did Boston Scientific --

THE COURT: Well, --

MR. LOVE: Excuse me. I'm sorry.

THE COURT: Let me rule on it.

Counsel, I think with respect to an expert witness, leading is permissible. I'm going to overrule the objection in the interest of time and given the subject matter of where we are, Mr. Adams.

BY MR. LOVE:

Q. Irrespective --

THE COURT: Go ahead, please.

MR. LOVE: Thank you, Your Honor. I apologize.

BY MR. LOVE:

Q. With respect to future sling polypropylene materials, whether it's polypropylene or some other material, what did Boston Scientific say they were going to do in the future?

A. They were going to do clinical trials in a variety of clinical situations.

Q. Okay. Let's pull up the polypropylene slide. And can we click -- while he's getting that ready, let's just keep moving

on. You talked about a class of mid-urethral slings with Mr. Adams. Do you recall that testimony?

A. Yes.

Q. And he said that there were like 62 or something other mid-urethral slings in this category where some of them didn't have human testing as well. Do you remember that testimony?

A. Yes, I do.

Q. What was different about the Obtryx sling that made testing a requirement?

A. Several things. First of all, the ProteGen sling, as we've talked about, which they had already had experience with and withdrew from the market because of safety problems and problems as well with usage of it by physicians. And, so, they had that experience and had included, as we were just saying, internally that they realized they needed to do clinical testing in the future.

The de-tanged mid section of the Obtryx sling was different. That needed to be examined.

The other very important point is that because there hadn't been -- in part because there had been no clinical trials done prior to marketing of many of these slings, particularly long-term, there were even, even post-marketing when clinical trials were done. There were short-term results. But as long-term data started -- longer term, I should say, data started to come in because there's still a

lack of adequate long-term data, serious complications began to be seen.

And those type -- and serious complications were available in the literature at the time of development of the Obtryx sling which, again, was a reason for them to test the Obtryx sling to see if it was going to be safe for use.

Q. Perfect, perfect. So, there were differences between the Obtryx sling and the other mid-urethral slings?

A. That's correct.

Q. Okay. Let's go to the MSDS if we can real quick. Let's go ahead and pull up -- do you have the PowerPoint? There you go. Perfect. Okay.

Now, there were some questions about this that in the '90s the MSDS didn't contain this warning. Do you remember that line of questioning?

A. Yes, I do.

Q. But it did in 2004; right?

A. That's correct.

Q. Okay. Because there's no warning in the '90s, is it okay to ignore it when it appears in 2004?

A. No.

Q. Okay. Was there any scientific basis to conclude that polypropylene was safe for permanent human implantation in the pelvic region?

A. No, there was not.

Q. Okay. Let's go to the last page of the particular MSDS, if you'll go ahead and highlight that.

"This information is furnished upon condition that the person receiving it shall make his own determination of the suitability of the material for his particular purpose."

What does that tell the reader or the purchaser of the polypropylene material in 2004?

A. It's telling the purchaser, in this case Boston Scientific, that they needed to determine the suitability of the product for permanent implantation. And, in fact, there was a contract, the contract for sale of the polypropylene for use in Boston Scientific slings also stated that to the best of my recollection.

Q. Okay. You mentioned a Ms. Rao, Doreen Rao. She's going to testify tomorrow here. And he mentioned that she did an investigation herself and determined that the language had no scientific basis; right?

A. Yes.

Q. Okay. Is there any scientific evidence establishing that polypropylene is safe in the pelvic region at the time Ms. Rao did her investigation?

A. No.

Q. Okay. I think he mentioned something about it was done for legal purposes, legal language. Do you understand that Chevron Phillips was concerned about these very types of

lawsuits and that's why they required the language?
A. That's correct.
MR. ADAMS: Lack of foundation and speculation, Your Honor.
THE COURT: There is an objection, counsel. Do you want to respond to it?
BY MR. LOVE:
Q. Are you aware of why the legal language was --
THE COURT: Is there a response to the objection?
MR. LOVE: I can rephrase my question, Your Honor.
THE COURT: He is withdrawing that question, Mr. Adams, and asking another one. Go ahead, please.
MR. ADAMS: Thank you, Your Honor.
BY MR. LOVE:
Q. Are you aware of why the language was added?
A. I have -- some of the information that I've reviewed has indicated it was because of product liability concerns.
Q. Okay. Let's talk about that AUGS statement again.
If you could, Mr. Adams, if your technical person could assist us.
MR. ADAMS: Sure.
MR. LOVE: If you could pull that up and we need to make a switch here real quick. I'm almost done. I've just got two or three questions on this just to make sure we're on the same page.

(Pause)

MR. LOVE: I think it's 1230.

MR. ADAMS: You're right. It is 1230.

MR. LOVE: Perfect. Thank you very much.

BY MR. LOVE:

Q. Okay. First of all, this is an editorial; right?

A. That's correct.

Q. This is an opinion piece by these five guys?

A. That's correct.

Q. Okay. This is not based upon a scientific analysis of the safety literature that's available with respect to the Obtryx sling, for instance?

A. That's correct.

Q. It's not a scientific piece that's based upon an analysis of all the available scientific literature that's available on mesh polypropylene?

A. That's correct.

Q. Okay. This is done by Boston Scientific consultants who write an editorial about what they think is appropriate for mid-urethral slings?

A. Yes, two of the authors, that's correct, had a connection with Boston Scientific. And one of them, Dr. Miller, was receiving royalties for his part in developing another mesh product.

Q. Another mesh product?

A. Of Boston Scientific.
Q. Okay, okay. Let's go to the second page if we can. I know there was a statement you wanted to make a comment on and I want to -- if we can go to the second page. And I believe it's that -- if you could highlight this first top paragraph on the left. Perfect. All right, great. All right.
BY MR. LOVE:
Q. So, that statement was read to you about a 17-year study that was done?
A. Yes.
Q. What was the product in that 17-year study?
A. That was the -- that was the original retropubic sling developed by Ulmsten and ultimately marketed by Ethicon. And the --
Q. So, it's an Ethicon product, which is J&J I think; right?
A. That's correct.
Q. Johnson & Johnson?
A. That's correct.
Q. It's called a TVT?
A. That's correct.
Q. All right. So, it's a different product?
A. That's correct.
Q. Made by a different company?
A. That's correct.
Q. And, so, does it deal with the Obtryx at all?

A. No. In fact, the insertion route is totally different as well.
Q. Were there any Obtryx slings involved in that study?
A. No.
Q. Okay. Now, you said you wanted -- you had a few comments when Mr. Adams was talking to you about this, but you didn't get an opportunity to talk about them. What are your comments about this AUGS position paper editorial?
A. Several. First, with that statement we were just talking about with the durability, safety, and efficacy up to 17 years. That 17-year review was on a small number of patients and was flawed because there were a number of patients that were lost follow-up. And, so, the 17-year safety, efficacy, durability was not known for that patient.

And from my experience of many years conducting clinical trials, when patients are not available for giving -- when they're lost follow-up, they're not available for ascertaining what their long-term durability is or safety or efficacy. You don't know if it's because the product really didn't work very well for them or because they liked it.

So, there are a lot of open questions there.
Q. Let's just get to the chase. Did that 17-year study, was it done on Obtryx slings?
A. No.
Q. Okay. It was done on a different product, TVT?

A. That's correct.
Q. Did this TVT 17-year study, did it have de-tanged edges?
A. No.
Q. Okay. Different product, different design, different company.
A. That's correct.
Q. All right. Any other comments on the AUGS statement that you need to clarify?
A. Yes, a number. It's not fair and balanced. It discusses the 2000 publications and it discusses that the scientific literature provides evidence of safety and effectiveness. And the literature is very mixed. And there are authoritative statements that the literature is lacking randomized controlled trials that are long-term. The data is mostly short-term.

As this statement was being written, there were a number of publications coming out in that time frame showing serious complications with mid-urethral slings.

Q. Okay. Listen, you've been up there a long time today. I appreciate your time and your patience.
A. Thank you.

THE COURT: You can step down, ma'am.

THE WITNESS: Thank you, Your Honor.

THE COURT: Call your next witness.

MR. LOVE: Your Honor, at this time, we would call

Rob Miragliuolo. He is the Vice President of Regulatory Affairs and his deposition time is 21 minutes.

(The videotaped deposition of Robert Miragliuolo was played for the jury.)

MR. MONSOUR: Your Honor, that concludes the offer for Mr. Miragliuolo. At this point in time, it's 10 till. We've got two videos --

MR. STRONGMAN: Boston has a two-minute counter.

MR. MONSOUR: I'm sorry. I thought yours was included.

MR. STRONGMAN: But it's short.

MR. MONSOUR: Okay.

(The videotaped deposition of Robert Miragliuolo continued to be played for the jury.)

MR. STRONGMAN: That concludes Boston Scientific's.

THE COURT: All right. Thank you.

Ladies and gentlemen of the jury, I'm going to release you for your evening recess. While you're out, do not discuss the case among yourselves or permit anyone to discuss it with you or in your presence. And remember that you are not to listen to, view, or read any news media coverage that there might be of the trial.

Have a good, restful evening and I will see you at 9:00 a.m. tomorrow morning.

Yes, ma'am.

A JUROR: We just have court tomorrow and Wednesday; correct? We don't have it Thursday and Friday.

THE COURT: Yes, ma'am.

A JUROR: Thank you.

THE COURT: You're welcome. You all have a good evening.

(Jury left the courtroom at 4:52 p.m.)

THE COURT: Mr. Adams, you made an objection during the course of Dr. Pence's testimony. You had asked her regarding whether or not she, her research had -- if she had researched to see if the same component had been used. I -- she answered you. You then asked that I strike the remainder of her answer which I refused to do, and I told you that I would address it at the bench if necessary.

I simply wanted to place on the record her answer went to the effect, and I don't quote her exactly, that they were not marketing the product, but marketing the Obtryx sling and it needed to be tested in its current composition. When she referred to product, I understood that she was referring to the composition, not the Obtryx itself.

It was that portion of the answer that she did not answer to you "yes" or "no" as to whether or not she had researched to see if this, the current Obtryx was made out of the same component. She indicated it did not matter to her because they were not marketing the product but marketing the

Obtryx sling and it needed to be tested in its current composition to determine if appropriate to be marketed.

I denied your motion to strike the, that portion of her answer. And I did so believing that she was answering you "no" without specifically saying "no" and then giving her explanation as to why. And I simply wanted to place that on the record for you.

Are there other matters that need to be addressed here this evening?

MR. MONSOUR: I would like to give you the four points memo. I think you admitted the first page. I was not clear whether you entered the first page or the entirety of the document.

MR. ADAMS: Only the first page was offered.

MR. MONSOUR: So, what I did, Your Honor, pursuant to our discussion earlier, is I have marked through in a pen so you can see what's being marked out underneath pretty clearly the references that have the FDA. And I was just going to hand you this and let you look at it. And maybe we could address it real quickly in the morning if Mr. Adams had any objections.

THE COURT: We can address it now. I believe that I indicated to you that I wanted to see your redactions and then I would make a ruling on the admissibility of the document.

MR. MONSOUR: Thank you, Your Honor.

THE COURT: And have you shared this with Mr. Adams as well?

MR. MONSOUR: Yes.

MR. ADAMS: He has. And I guess my position on it, Your Honor, I think we got into this whole line of -- well, the whole issue on this document is -- I believe the Court's ruling is that it's relevant to show that Boston Scientific recognized, if we look at the last bullet point on the first page, recognized that after the ProteGen experience we needed to do future clinical data.

The plaintiffs have already got into evidence that there was a recall, and I don't think that the rest of the document is -- well, under a 403 analysis I don't think you need to admit this document.

So, for example, it asks questions about, "Why was the ProteGen recalled?" That's really irrelevant. They've already proven their point that it was recalled. And, again, the message on the key take-away that we would do future performance, they've made that point too.

Again, the problem with redacting the FDA is the recall was done pursuant -- well, the recall is tied to FDA action. And, so, that's what I think makes the rest of the document very prejudicial.

And, again, I think that the points that, for which the document was admitted have already been made by the first

page of the document that was offered by Mr. Love. That's all I'll say on it.

THE COURT: Mr. Monsour.

MR. MONSOUR: My response to that, Your Honor, would be -- I talked earlier and I'm not going to waste your time, the basis for admissibility of the ProteGen issue.

This document is a little different. This document talks about their conduct before with slings and sets up the subsequent conduct.

If you look through that document, one of the claims that we have in this case is a claim for gross negligence, punitive damages. If you look at that document, you will see that with regard to that document, they recall this product. They say they're going to do -- they are going to do future clinical studies on sling materials.

But then they also say in that document, "We deny that this -- we deny that this product is faulty and we will defend it in lawsuits." It's the same thing they're doing here.

And we have a claim for gross negligence in this case. And the motion for summary judgment on that claim was denied. Therefore, we are allowed to proffer evidence of gross negligence and conscious indifference in this case.

And because we are allowed to offer that, this document specifically shows a conscious disregard, a

continuing conscious disregard by the company for the safety of the women that its products are intended for. And that is one of the primary bases that I would like this document entered, Your Honor.

THE COURT: All right, counsel, I have previously ruled that the information contained in the document went to the defendant's knowledge and was probative on the issue of punitive damages.

I have reviewed it in the position that it was given to me, or the condition that it was given to me with the proposed redactions in it. I believe that those redactions take care of the issues outlined in Judge Goodwin's pre-trial orders. And I am, therefore, going to admit the document in its entirety, preserving, Mr. Adams, your objection and exception with the redactions done.

Mr. Monsour.

MR. MONSOUR: Yes. If you will give that to me, Your Honor, I will get a clean version tomorrow and we will proffer it first thing.

THE COURT: I was hoping to take it home with me.

Anything further you all want to cover this evening?

MR. ADAMS: No. And I appreciated your clarification on my objection on Dr. Pence. And I will also acknowledge that my objection should have been better. I should have moved -- I should have said, "Objection, nonresponsive." And

I will do that in the future because I, I think that might have caused the confusion by the Court. So, I apologize.

THE COURT: Well, to be perfectly candid with you, that is how I construed it. But because I believe she impliedly answered "no" when she gave the explanation, that was my reason for not striking the answer as you requested.

MR. ADAMS: Very good.

THE COURT: You all have a good, restful evening and I'll see you at 9:00 a.m. tomorrow.

MR. MONSOUR: Thank you, Your Honor.

(Trial recessed at 5:00 p.m.)

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REPORTERS' CERTIFICATE

Carol Farrell, CRR, RMR, CCP, RPR, RSA, Official Court Reporter of the United States District Court for the Southern District of West Virginia, and **Lisa A. Cook, RPR, RMR, CRR, FCRR,** do hereby certify that the foregoing is a true and accurate transcript, to the best of our ability, of the proceedings as taken stenographically by and before us at the time, place, and on the date hereinbefore set forth.

/S/ Carol Farrell, CRR, RMR, CCP, RPR **11/03/14**
Court Reporter **Date**

/S/ Lisa A. Cook, RPR, RMR, CRR, FCRR **11/03/14**
Court Reporter **Date**

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